BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	)	
Roberto Victor Illa, M.D.	)	Case No. 800-2014-004467
Physician's and Surgeon's Certificate No. G 22683	)	
Respondent	)	

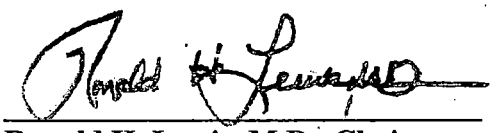
DECISION

The attached Decision is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on February 16, 2018.

IT IS SO ORDERED: January 17, 2018.

MEDICAL BOARD OF CALIFORNIA



Ronald H. Lewis, M.D., Chair
Panel A

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: ROBERTO VICTOR ILLA, M.D., Physician and Surgeon's Certificate Number G22683 Respondent.	Case No. 800-2014-004467 OAH No. 2016050762

PROPOSED DECISION

A hearing convened in this matter before Marilyn A. Woollard, Administrative Law Judge (ALJ), Office of Administrative Hearings (OAH), on August 21, through August 24, 2017, in Sacramento, California.

Mara Faust, Deputy Attorney General, appeared on behalf of complainant Kimberly Kirchmeyer, Executive Director of the Medical Board of California (Board), Department of Consumer Affairs.

Respondent Roberto Victor Illa, M.D., was present and represented himself.

Oral and documentary evidence was received. At the conclusion of the evidentiary hearing, the record remained opened for written closing arguments. Respondent's Closing Brief was marked for identification as Exhibit O. Complainant's Trial Brief and Reply Brief were marked for identification, respectively, as Exhibits 20 and 21. Respondent did not submit a reply brief. Pursuant to the August 24, 2017 Case Status and Briefing Order, the record remained open through November 30, 2017. The record was then closed and the matter was submitted for decision on November 30, 2017.

FACTUAL FINDINGS

1. On July 14, 1972, the Board issued Physician's and Surgeon's Certificate Number G 22683 to Roberto Victor Illa, M.D. (respondent). This certificate is renewed and current, with an expiration date of May 31, 2019. There is no prior history of discipline.

2. On March 3, 2016, complainant signed and filed the Accusation in this matter, seeking to discipline respondent for gross negligence, repeated negligent acts, and failure to maintain accurate medical records regarding his care and treatment of patient SVT from January 2011, through March 2014, pursuant to Business and Professions Code sections 2234 and 2266.[1]

The Amended Accusation, as further amended at hearing (Finding 5), alleges that respondent diagnosed and treated SVT for type 2 diabetes mellitus (diabetes) from April 28, 2008, until September 30, 2011. When SVT returned to respondent's care on January 15, 2014, respondent withdrew this diagnosis, and diagnosed her with nesidioblastosis. Respondent continued to treat SVT through March 2014. Complainant alleged the following acts by respondent, considered collectively, constituted gross negligence: withdrawing his diagnosis of diabetes for SVT from January through March 2014; failing to adequately document a basis for SVT's alleged hypoglycemia; diagnosing SVT with nesidioblastosis; failing to order certain tests for SVT; and failing to maintain accurate and complete medical records for SVT, including by failing to document a foot examination. These same acts, or a combination of at least two of these acts, were alleged to constitute repeated negligent acts, and respondent allegedly failed to maintain accurate and complete records of his care and treatment of SVT from January through March 2014.

3. On April 1, 2016, respondent filed his Notice of Defense. The matter was set for hearing and continued twice, due to the unavailability of respondent's counsel (June 8, 2016 Order) and following the withdrawal of respondent's counsel (January 11, 2017 Order). Respondent then proceeded to represent himself and to act as his own expert witness.

4. On June 2, 2017, respondent filed a motion for summary judgment and dismissal of the Accusation. On June 29, 2017, respondent filed a Rebuttal to Accusation. In both pleadings and throughout the hearing, respondent asserted that his professional opinion in the form of his nesidioblastosis diagnosis for SVT was protected from retaliation or discipline by Business and Professions Code sections 2056 and 2234.1. These motions, as well as respondent's motion to remove the Accusation from the Board's website, were denied as premature and as requiring determination on a full evidentiary record.

By Order dated August 16, 2017, complainant's motion to exclude the medical records of a different patient, which respondent argued demonstrated the appropriateness of his nesidioblastosis diagnosis of SVT, was granted. Respondent's motions for an order to test SVT by newer technology to diagnose hyper-insulinemic states, such as nesidioblastosis, to strike any reference to the theory of "insulin resistance," and to strike various allegations respondent asserted were inaccurate were denied. Respondent's request to strike the allegation that nesidioblastosis is "widely debated by diabetic experts as to whether it exists

[1] The initials of respondent's former patients are used to protect their privacy. Their names are subject to the January 2, 2018 Second Amended Protective Order, which incorporates the December 5, 2017, Amended Order Regarding Confidential Patient Names and Amended Confidential Names List.

at all" was granted. Complainant was ordered to file an Amended Accusation to strike the above-quoted allegation and to correct previously identified date errors.

5. In response to this order, complainant filed an Amended Accusation on August 21, 2017. During the hearing, the Amended Accusation was further amended to delete allegations that respondent's medical records were not "legible," and to substitute the word "complete" for "legible." An additional date change at page 5, paragraph 21, line 27, was made by interlineation, by striking "January 2011" and replacing it with "January 2014."

6. At hearing, complainant called SVT, Investigator Adam Brearley, Marc Gregory Jaffe, M.D., and David Lewis Geffner, M.D., as witnesses. Respondent testified on his own behalf and called Stanley Eric Lieberson, Ph.D., and former patients TCC, KE, and MS as witnesses. Their testimony is summarized as relevant below.

Complaint and Investigation

7. On April 15, 2014, SVT filed an online complaint with the Board about respondent's treatment when she returned to his care in 2014, with complaints of weight loss, pain in her feet, arms and hands, and very high blood sugars. SVT reported respondent told her she never had diabetes, but had a disease called nesidioblastosis, which caused all her symptoms and which he should be able to cure with pills. He gave SVT a flyer, told her to buy his book for more information, and reported that he had discovered hundreds of people in Butte County who had this condition. Respondent had SVT take a four-hour blood test and he recommended a brain scan, which her insurance did not cover. He switched SVT's pills for diabetes and took her off one of her depression medications. SVT concluded: "My blood sugars got up to over 600 for two weeks [*sic*] I finally went to the hospital and they gave me insulin and asked how was I still alive with blood sugars that high."

8. On June 11, 2015, respondent participated in a recorded interview with Board Investigator Adam Brearley, Board's medical consultant, Howard Slyter, M.D., and Ms. Faust. Investigator Brearley later sent the case out for review to two experts: Marc Gregory Jaffe, M.D., who prepared an August 20, 2015 expert report, and David Lewis Geffner, M.D., who prepared a November 10, 2015 Report and an Addendum dated December 12, 2015. Both experts reviewed documents provided by Mr. Brearley, including SVT's complaint, medical and pharmacy records; respondent's Board interview (audio and transcript); excerpts from respondent's book, "Disorders of Blood Sugar: The Illa Protocol" (4th edition, 2012); and articles and a slide presentation about nesidioblastosis cited by respondent.

In his report, Dr. Jaffe concluded that respondent had engaged in three simple departures from the standard of care: (1) by failing to diagnose SVT with diabetes on four occasions from January 15, through March 21, 2014; (2) by ordering a glucose tolerance test for SVT on two occasions in 2014, to identify hypoglycemia in a patient with preexisting diabetes who was taking multiple anti-hyperglycemic medications; and (3) by concluding that SVT had nesidioblastosis in the absence of documented hypoglycemia. In his reports,

Dr. Geffner opined that respondent engaged in multiple extreme departures from the standard of care regarding his tests and referrals, medical documentation and selection of treatment for SVT.

SVT's Treatment Records

A. April 28, 2008 through September 2011

9. Respondent's April 28, 2008 progress note detailed his initial evaluation of 22-year-old SVT, whose primary care provider was Physician's Assistant (PA) Marilyn Slater at Del Norte Clinic/Ampla. SVT had been diagnosed with diabetes "two months ago"; had never been hospitalized and had no kidney failure. Her highest blood "sugar was in the 290's, with the lowest sugar of 70 mg% three weeks ago." SVT's chief complaint was of being tired all the time. Other significant problems noted were obesity (255 pounds, with a 73 pound weight gain in the past two years), and "neuropathy: intermittent pain and numbness in feet." SVT was on Metformin 1,000 mg twice daily, an oral medication for type 2 diabetes, which caused her diarrhea. Respondent conducted a history, review of systems and physical examination. In the physical examination, he noted SVT had no edema, was ambulatory without gait disturbance and had "light touch intact on both feet."

Respondent's assessment was: type 2 diabetes mellitus; obesity; depression; early diabetic peripheral neuropathy; history of chronic low back pain; diarrhea secondary to Metformin; insomnia; anxiety; and probable hyperventilation syndrome. His plan was to stop Metformin. He prescribed two daily oral medications for type 2 diabetes (Actos 45 mg and Januvia 100 mg) and ordered predictive panel lab work.

10. Respondent's May 12, 2008 progress note documented SVT's April 29, 2008 lab results as: "HgbA1c 6.3. C-Peptide 6.6." SVT reported getting up every hour to urinate. He reiterated the previous assessment, with the primary diagnosis of type 2 diabetes, early. In this and other progress notes, respondent instructed SVT to "F/u with primary care doctor." On June 12, 2008, SVT reported feeling better. Respondent kept the same diagnoses, but added: "nocturia." SVT's diabetic medications remained the same; she was also taking Zoloft 50 mg once daily. On September 2, 2008, SVT reported her blood sugar had been between 85 and 120 on her home glucose meter for the past several months. Her Zoloft dosage increased to 75 mg per day, and she reported sleeping 14 hours per day. Respondent's assessment and plan was the same, but he added "Fatigue from Zoloft." On November 5, 2008, SVT reported having more energy. Respondent added Bupropion 75 mg daily, Trazodone 50 mg at bed for insomnia, and Tramadol 50 mg once or twice daily for back pain. His assessment and plan were the same.

11. On January 6, 2009, respondent noted SVT had been off Actos for one month and was also off Trazodone. He substituted Ambien prn, and added "viral URI [Upper Respiratory Infection] and viral bronchitis" to the assessment. On February 23, 2009, SVT reported that her blood sugar has been "kind of high" and she was not eating on a regular basis. No current blood sugars were recorded, and the assessment and plan were unchanged.

On April 22, 2009, SVT reported drinking heavily on weekends and binging on chocolate. Noting her weight was up to 281 pounds, respondent instructed SVT to "see a counselor regarding compulsive eating disorder." On September 25, 2009, SVT reported feeling pretty good and sleeping a lot. Under assessment, respondent noted viral URI and bronchitis was resolved. The assessment and plan remained unchanged. On December 8, 2009, SVT reported feeling "dizzy." She weighed 303 pounds. The assessment and plan remained unchanged.

12. On January 26, 2010, SVT reported that her "blood sugar is going up." The assessment was unchanged. Respondent increased Actos to 45 mg daily and prescribed Onglyza 5 mg daily to control blood sugar. On July 12, 2010, SVT reported having had three sinus infections in a row. She got laid off and ran out of both Actos and Onglyza four months ago. Her current medications were Metformin 500 mg bid. Her weight was 303 pounds. Respondent's assessment was the same, but his plan was for SVT to stop Metformin and begin daily Actos 15 mg and Onglyza 5 mg. On September 2, 2010, SVT reported feeling well and being back in school. Her current medications were daily Actos 15 mg and Januvia 100 mg. Her weight was reported as "193.6 [*sic*]" pounds, with a height of 71.5 inches. The assessment was the same. SVT was to continue daily Actos 15 mg and stop Januvia 100 mg. On November 29, 2010, SVT reported feeling well. Her current medications were Actos 15 mg daily. Her weight was 296.2 pounds. There was no change to the assessment or plan.

13. On March 10, 2011, SVT reported binge eating candy. Respondent's assessment was unchanged; he added "Diet and exercise" to the plan. On September 30, 2011, SVT reported she had sprained her right ankle in June, had stopped Actos and was on Metformin 500 mg twice daily, as recommended by PA Slater. She weighed 290.6 pounds. Respondent's plan was "trial of Metformin and check sugar. Diet and exercise."

B. <u>January through March 2014</u>

14. On January 15, 2014, SVT returned to respondent, with complaints of:

> **Being dizzy x 1 week**. She has very severe pain in her feet which keeps her up at night. Using an Accu-chek Nano. No impairment of concentration. **Impairment of short-term memory**. Has not lost consciousness. Has not had adult-onset epilepsy. **Has had blurring of vision or double vision. Has had weakness or paralysis of facial/limb muscles. (L.arm) this comes and goes. Has muscle twitching. (Both feet and both legs). This is not all the time. 1 yr. +. . . . Has episodes of irritability or emotional outbursts. (7 yrs). . . . Becomes dizzy or lightheaded often.** Has not been disoriented. **Pt feels fatigued. (10 yrs). No MI. No CVA. No TIA. . . .**

(Bolding in original.)

SVT reported the following blood sugar numbers: 247, 204, 155, 216, 283, 174, 243, 262, 306, 172, 183, 125, 167. Respondent reviewed SVT's previous problem list, with her primary problem of diabetes. SVT's current medications included the diabetic oral medications Glimepiride 2 mg daily and Metformin 1,000 mg bid, as well as daily Zoloft 100 mg and Wellbutrin 75 mg. SVT's April 29, 2008 A1c of 6.3 and C-Peptide of 6.6 was recorded, along with the notation: "12/5/2013 eGFR 110 C-Peptide 7.89 (0.80 – 3.10 ng/mL). Respondent documented a brief physical examination, noting SVT weighed 289.8 pounds.

Respondent's assessment was: "1. **Probable Nesidioblastosis**. 2. Obesity. 3. Depression; treatment. 4. Early diabetic peripheral neuropathy. 5. History of chronic low back pain. 6. Diarrhea secondary to Metformin. 7. Insomnia. 8. Anxiety. 9. Probable hyperventilation syndrome. 10. Nocturia. 11. Fatigue from Zoloft." (Bolding in original.) His plan was for SVT to take Pioglitazone (Actos) 30 mg daily and Onglyza 5 mg daily; and to stop taking Glimepiride, Metformin, and Gabapentin. Respondent ordered the following fasting laboratory testing: "4 hr. GTTID . . ."[2] SVT was instructed to: "Use Accu-chek home glucose meter to check your blood sugar. Do this twice daily. Bring your meter to every visit."

15. On February 10, 2014, SVT reported "two bad emotional episodes." She was not going back to work and had forgotten to take her pills. SVT reported her lowest blood sugar numbers as 279 and her highest as "over 600 mg." She had "Nocturia 10+" and reported having "very severe pain in her feet which keeps her up at night." Respondent documented a brief physical examination. His assessment of "probable Nesidioblastosis" remained unchanged.

Respondent's four-page progress note for this visit included the results of SVT's February 4, 2014, fasting GTTID from Quest laboratory:

Time	Pt Insulin	Insulin Range uU/mL	Pt Glucose	Glucose Range mg/dL	Pt Glucagon	Glucagon Range pg/mL
Fasting	17.0	‹ 23	348.0	70-140	‹ 134.0	‹ 134
1/2 Hour	27.0	6 - 86	449.0	70-140	196.0	‹ 134
1 Hour	24.0	8 - 112	457.0	70-140	170.0	‹ 134
2 Hour	19.0	5 - 55	418.0	70-140	194.0	‹ 134
3 Hour	33.0	3 - 20	379.0	70-140	181.0	‹ 134
4 Hour	24.0	‹ 15	350.0	70-140	193.0	‹ 134

[2] Respondent's book characterizes the Glucose Tolerance Test with Insulin Determinations or GTTID as the "only test . . . that qualifies as reliable in defining diabetes mellitus. . . ."

Under Plan, respondent adjusted SVT's medication by having her: (1) start "Bydureon 2 mg sc" (a non-insulin treatment for type 2 diabetes); (2) start a trial of either of these oral diabetes medications: Starlix 60 mg tid (three times daily) or Prandin .5 mg tid before meals, with a notation: "if symptoms of low blood sugar appear (like dizziness or tremulousness, weakness etc. stop taking these meds); (3) continue Pioglitazone (Actos) 30 mg daily; and (4) "**Increase** Onglyza 5 mg to twice daily (May take Januvia 100 mg)." SVT's other medications were continued. Respondent further instructed SVT to:

> Avoid clear water for hydration. Use Gatorade.
>
> Use Accu-chek home glucose meter to check your blood sugar. Do this twice daily. Bring your meter to every visit.
>
> Dexcom CGM [continuous glucose monitoring] testing.
>
> Non-contrast Brain MRI.

16. On March 2, 2014, SVT was seen at Enloe Medical Center's Prompt Care for an evaluation of high blood sugar. SVT advised PA Elena Ortiz that respondent had diagnosed her with nesidioblastosis.[3] SVT reported being on multiple hypoglycemic medications, with no insulin or injectables, and that her blood sugar had been over 300 for the past few weeks and 600 for the past three days. She also reported a sinus infection.

SVT's blood sugar was checked and measured as 421. On physical examination, SVT was described as morbidly obese. She reported drinking two large Gatorades with her food. After being given 10 units of regular insulin subcutaneously, SVT's blood sugar dropped to 362 within an hour. After being administered another 10 units of regular insulin, SVT's blood sugar decreased to 294 and she was stable at discharge. The assessment was: "(1) Hyperglycemia, history of nesidioblastosis. (2) Sinusitis." SVT was instructed to follow up with respondent the next day so her oral medications could be adjusted.

17. In his March 10, 2014 progress note, respondent documented SVT's report of feeling tired and "out of it" with no energy. She was on 14 units of Lantus (glargine insulin injection, long-acting), with "Nocturia 5 to 6." Respondent changed his assessment to Nesidioblastosis (removing "probable") and he continued his prior assessments. The plan was to reduce Lantus insulin to 12 daily units, with notations to "slowly reduce dose as blood sugar peak declines," and to start "Symlin Pen 60. Inject 15 mcg once daily. Increase to 30 mcg in 7 days if no nausea." SVT was instructed to continue home glucose meter checks for blood sugar twice daily.

18. SVT's last visit with respondent was on March 21, 2014. She reported being "mad about her condition so has not been testing. Problems with short-term memory.

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[3] Despite a notation to this effect in her Enloe medical records, SVT clarified that respondent never told her that he was an endocrinologist.

Misplaces things. Feet still hurting on and off. Perspires. No dizziness in last 24 hrs. . . ." She reported her blood sugar as 352 that day. "Did not check yesterday. 424, 410." SVT's current medications included Lantus insulin 35 units daily; "Symlin Pen 60. Inject 30 mcg one daily. Increase to [*sic*];" Pioglitazone 30 mg daily; and Onglyza 5 mg bid. Respondent's assessment remained unchanged. The plan was to increase Lantus insulin to 40 units daily, with a notation to slowly reduce dose as blood sugar peak declines; inject 45 mcg daily Symlin Pen 60; Pioglitazone 30 mg daily and "Onglyza 5 mg to twice daily (May take Januvia 100 mg)." Respondent noted: "Laboratory testing. GH, Delta Glucagon, TSH, Comprehensive profile." SVT was to return in three to four weeks, but did not do so.

On April 1, 2014, SVT participated in the lab test ordered by respondent. Her results included: a C-Peptide level of 2.77, a fasting Glucose level of 266; a fasting Glucagon level of 156; and a two-hour postprandial Glucagon of 199.

SVT's Testimony[4]

19. SVT's testimony was largely consistent with her on-line complaint. She receives her primary health care at Ampla, where PA Slater first diagnosed her with type 2 diabetes in 2006. After PA Slater left, SVT was then treated by Dr. Dorgee. Her current treating physician is Dr. Sandhu. Between 2006 and 2014, SVT was treated by these Ampla health practitioners approximately 10 times a year.

20. From 2008 through 2011, respondent told SVT that she had type 2 diabetes. SVT thought respondent was "a great doctor" who helped her. In addition to his medical care, respondent would talk with SVT about her art work, and he seemed to "really care" about her. If there were any medications she could not pay for, "all I had to do was call him and he would get my meds covered." During this time period, respondent adjusted SVT's diabetic medicines due to side effects. After she began seeing respondent, SVT did not have foot examinations by any other health care providers.

21. SVT stopped seeing respondent after September 30, 2011, because she was doing well. She decided to stick with the plan he had developed for her and continue to see her regular doctor. By the end of 2013, however, SVT started losing weight for no reason, even though she had not changed her diet or exercise habits. She was having normal diabetic symptoms like urinating a lot and feeling feet pain, which she attributed to neuropathy, and her blood sugar was very high, which was "scary." She tried to schedule an appointment with an endocrinologist, but Ampla could not find one through telemedicine who would accept Medi-Cal. This was the reason SVT decided to return to see respondent.

22. In January 2014, respondent told SVT that she had nesidioblastosis, a disease he had not known about before. He explained that this disease was causing all of her symptoms and she never had type 2 diabetes. He gave her a flyer that explained this new

[4] On the date she testified, SVT had taken two medications: Topamax, which affects short term memory, and Norco for neck and shoulder pain.

diagnosis.[5] SVT was "amazed and hopeful" because respondent had helped her to get so much better before. Respondent adjusted her diabetic medicines. SVT was happy and had the lab work done as ordered. At the time of the labs, she was on her diabetic medications.

23. At her February 10, 2014 visit, respondent discussed the February 4, 2014 lab results with SVT. He told her that her "blood sugar would go down very low for maybe a couple seconds and then shoot back up high. So you wouldn't see it on the labs, and he said that about the [home glucose] meter too later." He told SVT that people who did not take care of their nesidioblastosis have a portion of their brain taken out. He ordered an MRI brain scan; however, SVT's insurance would not cover it.

Respondent told SVT to avoid water and other clear liquids for hydration. Instead, she was only to drink Gatorade because she needed the electrolytes. Based on her history as a diabetic since 2006, SVT thought this did not make sense because Gatorade is a sugary drink. She argued with respondent, but then agreed. Respondent also told her she could have as much chocolate as she wanted. At this point, SVT did not believe respondent. He asked her to buy his book at most visits, but she told him she was a college student and did not have the money. SVT tried to believe respondent, but it just "wasn't making sense," especially because her blood sugars were going up and she did not feel good. SVT found it very frustrating because she had to keep arguing with respondent about this, at the same time that she felt guilty because he had helped her before. At some point, SVT and respondent got into a shouting match. Respondent was angry because she did not believe him.

24. Respondent told SVT that nesidioblastosis was going to cure her, or maybe not cure her, but she would not have diabetes anymore and she would get healthier. SVT's blood sugar never went down. She ended up with blood sugar of 600 for over two weeks, until her family talked her into going to the Enloe emergency clinic. There, the nurses seemed to be "scared and astonished" at her high numbers and the doctor was surprised she was not dead. When SVT told the Enloe doctor about respondent's diagnosis, the doctor told her that nesidioblastosis is something babies have and he had never heard of it in adults.

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[5] The one-page flier was an excerpt from "Adult-Onset Nesidioblastosis Causing Hypoglycemia: An Important Clinical Entity and Continuing Treatment Dilemma," June 2001, ARCH SURG. Vol. 136, by Witteles, M.D. et al. The authors describe their hypothesis as: "Nesidioblastosis is an important cause of adult hyperinsulinemic hypoglycemia, and control of this disorder can often be obtained with a 70 percent distal pancreatectomy." Their conclusion was: "Nesidioblastosis is an uncommon but clinically important cause of hypoglycemia in the adult population, and must always be considered in a patient with a presumptive preoperative diagnosis of insulinoma. This study indicates that a 70% distal pancreatectomy is often successful in controlling hypoglycemia, and rarely results in diabetes mellitus. However, the optimal treatment for this disorder remains to be determined."

25. When she saw respondent in 2014, SVT thought he was not as friendly as he had been before. Respondent "wasn't the same person" who used to talk about art and all kinds of things. Instead, he "just really wanted to talk about the book and this new disease." He was "just really focused on it," and would get angry and argue with SVT a lot, and yell at her. His personality seemed changed; he seemed less happy and carefree. SVT did not feel respondent was treating her like a patient. She felt like his test subject; as if "he was using me to add to his collection, to add to the book basically. . . ." SVT was now "upset, angry, depressed." For the first time in her life, she was on insulin. Doctors have told her she will be on insulin for the rest of her life.

26. SVT is currently diagnosed with type 2 diabetes. She is being followed by an endocrinologist, a dietician, and her primary care doctor. She lost 60 pounds in the last year, and her A1C is checked regularly. Her blood sugars are currently in a healthy range due to insulin. She is currently on four insulin shots a day and two oral medications, including Metformin. She believes the extremely high blood sugars she had in 2014 are the reason she cannot get off of insulin now despite her weight loss and healthy life style. SVT never sued respondent; she "just does not want him to hurt anybody else." She was unaware that the University of California (UC), Davis Medical Center operates a nesidioblastosis surgery center or that respondent has referred patients to this center.

COMPLAINANT'S EXPERT OPINIONS AND TESTIMONY

A. Marc Gregory Jaffe, M.D.

27. Dr. Jaffe obtained his medical degree from Baylor College of Medicine in 1988, and became licensed in California that year. He completed his internship and residency at UC San Diego School of Medicine, in internal medicine. From 1991 through 1993, Dr. Jaffe completed a fellowship and a post-doctoral research position in diabetes, endocrinology, and metabolism at UC San Francisco School of Medicine. Dr. Jaffe has been certified by the American Board of Internal Medicine (ABIM) since 1991, with most recent recertification in 2012. Since 1993, he has been ABIM-certified in Diabetes, Endocrinology, and Metabolism, with most recent recertification in 2013.

Dr. Jaffe has been a staff physician at Kaiser South San Francisco since 1993 and an attending physician at San Francisco General Hospital's (SFGH's) Endocrinology Clinic since 1994. He is an Associate Clinical Professor on SFGH's volunteer medical faculty. Dr. Jaffe has reviewed approximately six cases for the Board, finding for the physician in half of those cases. During his career, Dr. Jaffe has diagnosed nesidioblastosis many times, typically in patients who are status post-bariatric surgery. He has also evaluated and treated numerous patients who are not taking diabetes medications for a variety of hypoglycemic syndromes, including nesidioblastosis.

28. In his August 20, 2015 Report, Dr. Jaffe discussed four medical issues raised by respondent's diagnosis and treatment of SVT.

29. Diabetes Diagnosis and Withdrawal of Diagnosis: Dr. Jaffe described the standard of care for diagnosing diabetes during the relevant time period as follows:

> In 2008, the standard of care for the diagnosis of diabetes mellitus, as established by the American Diabetes Association, was to identify 2 or more elevated fasting blood glucose levels over 124 mg/dL, a 2 hour glucose level over 199 mg/dL after an oral glucose tolerance test, or a random blood glucose over 199 mg/dL in the setting of classic symptoms. An elevated A1C greater than 6.4% was added as an additional criterion in 2009. For people already taking medications to lower blood glucose, clinical judgment is needed, and if such a patient demonstrated high-normal A1C or high-normal glucose values it is reasonable to establish the diagnosis of diabetes. . . .

Based on his review of the medical records, Dr. Jaffe concluded that respondent extensively documented clinical data to support his April 28, 2008 diagnosis of SVT with type 2 diabetes, and his continuing diagnosis of "type 2 diabetes mellitus, early," on 15 subsequent occasions through September 30, 2011.[6] In his opinion, respondent appropriately diagnosed SVT with type 2 diabetes and there was no departure from the standard of care from April 28, 2008, through September 30, 2011.

30. Dr. Jaffe concluded that respondent engaged in a simple departure from the standard of care when he discontinued SVT's diabetes diagnosis on four occasions from January 15, 2014 through March 21, 2014, "despite extensive documentation clearly supporting the diagnosis of diabetes . . . ." Respondent's conduct constituted a simple departure: "because a specialist in diabetes routinely identifies and treats many conditions characterized by hyperglycemia, and should be able to recognize and label an individual with extensively documented criteria that clearly establish and confirm the diagnosis of diabetes."

31. Selection of Appropriate Diabetes Treatment: Dr. Jaffe reported that, once a diagnosis of diabetes is established, the standard of care is: "to recommend lifestyle changes, maintain a healthy weight (weight loss if overweight), and select medications to control hyperglycemia while balancing the potential adverse effects of the medications (such as hypoglycemia, weight gain, convenience, cost and other side effects). (see American Diabetes Association, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care 2014)."

For hypoglycemia in people with diabetes treated with glucose lowering agents, "the standard of care is to reduce the risk of hypoglycemia by changing to agents with less propensity to cause hypoglycemia, modifying the timing of the medications, modifying the

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[6] Documentation included: elevated blood glucose levels in the lab; an elevated A1C; elevated patient self-monitored blood glucose readings by report and as documented by meter download; treatment with multiple anti-hyperglycemic medications, including insulin; and symptoms suggestive of glycosuria such as Nocturia.

type and timing of calorie consumption, assessing blood glucose control targets, increasing the frequency of patient self-monitored blood or interstitial glucose monitoring, developing action plans for hypoglycemia, and/or referring to other resources. . . ." If acceptable blood glucose targets are not achieved using one medication, "the addition of one or more additional diabetes medications (including insulin as an option) is recommended."

For people with type 2 diabetes and severe hyperglycemia, "escalation of therapy and oral hydration with close monitoring with frequent blood glucose assessment is indicated, and initiation of insulin is appropriate if hyperglycemia or symptoms worsen or persist without improvement over a short period of time (days to weeks)."

32. In Dr. Jaffe's opinion, during his 20 evaluations of SVT from April 28, 2008, through March 21, 2014, respondent frequently adjusted the doses of her anti-hyperglycemic medications and he often changed diabetes medications in an attempt to control SVT's hyperglycemia. Respondent also "advised intensive non-insulin treatment and oral hydration with close (1 week) follow up of severe hyperglycemia on 2/10/2014." Dr. Jaffe found no departures from the standard of care in respondent's selection of appropriate diabetes treatment for SVT in 2014.

33. Evaluation and Treatment of Suspected Hypoglycemia: Dr. Jaffe broadly described the standard of care for evaluating and managing suspected hypoglycemia as: "to select appropriate patients for evaluation, organize the appropriate evaluation, interpret results, establish the etiology, and render treatment." Dr. Jaffe discussed two standards of care for evaluating and treating patients with suspected hypoglycemia: one is applicable to patients, like SVT, who are diabetic and are being treated with glucose lowering medications; the other pertains to individuals who are not taking medications known to lower blood glucose (spontaneous hypoglycemia). These two standards are well-recognized by endocrinologists in the field.

For suspected hypoglycemia in patients with diabetes treated with glucose lowering agents, the hypoglycemia diagnosis: "is generally established on clinical suspicion, most often without formal laboratory confirmation, though patient self-monitored blood or interstitial glucose monitoring (by reports or by meter downloads) are often used to help support the diagnosis."

> For suspected hypoglycemia in patients with diabetes treated with glucose lowering agents, the standard of care is to reduce the risk of hypoglycemia, most often by adjusting the use of glucose lowering agents. This is generally done by selecting agents with less propensity to cause hypoglycemia, modifying the timing of the medication, to modifying the type and timing of calorie consumption, assessing blood glucose control targets, increasing the frequency of home glucose monitoring testing, developing action plans for hypoglycemia, and referring to other

> resources (such as certified diabetes educators, dieticians, mental health providers, and others).
>
> If a hypoglycemia or suspected hypoglycemia persists after all glucose lowering agents are discontinued, then a formal evaluation for hypoglycemia can be undertaken to determine if the subject satisfies all three criteria for clinical hypoglycemia (referred to as "Whipple's Triad")[7]. . . .
>
> The standard of care is not to initiate provocative testing (either prolonged fasting or postprandial) to diagnose the presence or etiology of hypoglycemia in an individual known to be taking antihyperglycemic medication (especially insulin and insulin secretagogues).

34. During her treatment visits with respondent from January through March 2014, SVT had blood glucose levels in the hyperglycemic range, while she was on multiple anti-hyperglycemic medications.[8] Dr. Jaffe noted that respondent adjusted SVT's anti-hyperglycemic medications and instructed her "to monitor her home blood glucose readings frequently using patient self-monitored blood glucose and a continuous glucose monitoring system (CGMS), which met the standard of care for the treatment of suspected hypoglycemia in a person taking anti-hyperglycemic medications." As a consequence, Dr. Jaffe concluded respondent had not departed from the standard of care for treatment of suspected hypoglycemia in a person taking anti-hyperglycemic medications in 2014.

35. In Dr. Jaffe's opinion, however, respondent did not comply with the standard of care for evaluating suspected hypoglycemia during this same time period, because he initiated provocative testing while SVT was taking anti-hyperglycemic medications. Specifically, respondent: "ordered a glucose tolerance test on 2 occasions [January 14, 2014 and March 10, 2014], to identify hypoglycemia in this patient with preexisting diabetes mellitus while taking multiple anti-hyperglycemic medications (including glarine insulin and the insulin secretagogue nateglinide)." This was a simple departure from the standard of care. In Dr. Jaffe's opinion, the standard of care "would have been to continue to adjust the anti-hyperglycemic medications to improve the hyperglycemia and also reduce the likelihood of hypoglycemia." While it was not likely that SVT's anti-hyperglycemic medications could have been safely discontinued, "if they were discontinued and the patient still exhibited signs

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[7] Whipple's triad involves: recognizing that the patient's symptoms could be caused by hypoglycemia; documenting that the patient's plasma glucose concentration is low when symptoms are present using a precise method, not a home glucose monitor; and demonstrating that the symptoms are relieved by administration of glucose or glucagon.

[8] SVT's self-monitored blood glucose was: 125 to 306 mg/dL on January 14, 2014; 279 to 348 mg/dL with maximum serum glucose of 457 mg/dL on February 10, 2014; and 352 to 424 mg/dL on March 21, 2014.

or symptoms of hypoglycemia, then provocative testing (either fasting or postprandial) may have been appropriate at that time."

36. Diagnosis of Nesidioblastosis: Dr. Jaffe characterized nesidioblastosis as a "very rare disorder, most often encountered in infants, and in some adults after bariatric surgery." The standard of care for diagnosing nesidioblastosis is as follows:

> The diagnosis of nesidioblastosis is characterized by severe hypoglycemia in persons not known to be taking medications that increase insulin levels (such as insulin [*sic*] insulin secretagogues). If a blood glucose level is documented to be low in a clinical laboratory (not by self-monitored blood or interstitial fluid measurement), the diagnosis of nesidioblastosis can be confirmed when the following are documented simultaneously: serum glucose ‹ 55 mg/dL measured in a clinical laboratory, elevated insulin level › 3 microU/mL, c-peptide • 0.2 nmol/L, beta hydroxyl butarate • 2.7 mmol/L, proinsulin • 5 pmol/L, and negative oral hypoglycemic medicine screen. Additionally the patient should have a robust glucose response to glucagon injection administered in the setting of documented hypoglycemia. Also the patient should have absent insulin antibodies (need not be done simultaneously). If all these criteria are satisfied, then imaging of the pancreas (with CT, MRI, Angiography, endoscopic ultrasound, or other modality) can distinguish insulinoma from Nesidioblastosis.

37. A review of SVT's medical records for her treatment by respondent in 2014 revealed that she had "clinical laboratory documented elevated (not low) blood glucose levels on 2/4/2014 . . . of 348, 449, 457, 418, 379 and 350 mg/dL." Respondent diagnosed SVT with nesidioblastosis on March 10 and March 21, 2014, "with no documented blood glucose level in the clinical lab below 55 mg/dL." In Dr. Jaffe's opinion, this was a simple departure from the standard of care, based on respondent diagnosis of nesidioblastosis "in the absence of documented hypoglycemia."

In order to establish the diagnosis of nesidioblastosis, respondent: "would need to have demonstrated that after all glucose lowering medications had been stopped, all 3 of the following were present: blood glucose level below 55 mg/dL measured in a clinical laboratory, hypoglycemic symptoms, and improvement in symptoms when glucose normalized. If these preliminary criteria were met, then further testing to document nesidioblastosis would have been required . . . " as described above. However, "[b]ecause no blood glucose was documented below 55 in the clinical laboratory, the other metabolic tests cannot be interpreted as supporting the diagnosis of nesidioblastosis, and it is not possible to establish the diagnosis of nesidioblastosis. [Respondent] documented hyperglycemia and hyperinsulinemia which is most consistent with insulin resistance from type 2 diabetes."

38. Dr. Jaffe's Testimony: As discussed below, in his testimony, Dr. Jaffe expanded upon and modified the opinions he expressed in his report.

39. *Diabetes:* The American Diabetes Association (ADA) defines diabetes as established by one of the following four factors: two fasting blood sugars over 125 (formerly over 140); random blood sugars over 200 with clinical symptoms such as excessive thirst or urination; an A1C over 6.5; or an abnormal glucose tolerance test over 200 after two hours. The ADA suggests that the desirable range for blood sugar for a diabetic is "in the neighborhood of 80 to 120." This is difficult to reach for many type 2 patients; consequently, a blood sugar "range under 150 or 160 would probably be acceptable." The standard of care to accurately measure blood sugar level is in a certified clinical laboratory. Other ways to measure are by periodic hemoglobin A1C tests, which provide an average of the patient's blood sugar over the past three months, and by home monitoring, which is designed to guide patients in day-to-day decisions. There are two forms of home monitoring: home blood glucose monitoring, which is usually done on a finger, and interstitial fluid monitoring, also called continuous glucose monitoring (CGM), which measures the blood sugar between the cells via a catheter placed in the skin; it does not actually measure blood. In Dr. Jaffe's opinion, CGM is useful for patients, but is not reliable for diagnostic purposes; it is the least reliable way to assess a patient's blood sugar level.

40. Type 2 diabetes is a progressive disease. Type 2 diabetics who have elevated blood sugar over time can develop complications that primarily affect the blood vessels: (1) of the eyes, which can lead to blindness or other vision problems (retinopathy); (2) of the nervous system, which can lead to a lack of sensation or painful sensation in the feet and toes (neuropathy); or (3) of the kidneys, causing problems in or loss of kidney function (nephropathy). Keeping blood sugar in a healthy range reduces the chance of these serious complications.

41. On January 14, 2014, when she returned to respondent's care, SVT had "type 2 diabetes with poor control." This diagnosis was established by the fact that she had high blood sugars, above 200, while she was on two medications designed to lower her blood sugars (Glimepiride and Metformin). These facts are documented in respondent's progress notes. The February 4, 2014 Quest Lab results, documented in respondent's February 10, 2014 progress note, further confirms SVT's type 2 diabetes using two ADA criteria: (1) a random blood sugar over 200 in the presence of diabetic symptoms (SVT's fasting blood sugar of a 348, with nocturia 10 times a night); and (2) an oral glucose tolerance test where her blood sugar went "very high," over 400. Dr. Jaffe described this lab as a "provocative test" in which the patient is given sugar. Such test is not normally performed in patients like SVT who start out with high blood sugar diagnostic for diabetes. While SVT sought treatment from a diabetes specialist, respondent failed to diagnose diabetes.[9]

[9] Respondent's assessment of SVT in 2014 also included "diabetic neuropathy." Dr. Jaffe clarified that this refers to a nerve injury from diabetes, and is not a diabetes diagnosis.

42. The fact that SVT's C-Peptide levels were elevated confirms that she was making insulin, but had type 2 diabetes with insulin resistance.[10] In type 2 diabetes, patients' insulin levels may be high or low and their blood sugars may be high due to insulin resistance. These patients need higher amounts of insulin to keep their blood sugars down into a healthy range. The C-Peptide, which is part of the insulin molecule, is another way to measure insulin in the blood. Because it lasts longer in the body than insulin, it can be used as a footprint to identify how much insulin the patient is making over a certain time period. SVT's C-Peptide increased from 6.6 in 2008 to 7.89 in December 2013. Dr. Jaffe considered this to be "moderately elevated," but clinically irrelevant. Based on the peer-reviewed literature, an elevated C-Peptide level is not considered relevant in treating patients with type 2 diabetes. When the C-Peptide is normal or high, it confirms the diagnoses of type 2 diabetes and "is the hallmark of insulin resistance." Dr. Jaffe explained that this is "pretty standard science accepted without really any debate, any significant serious debate in the medical literature."

Dr. Jaffe agreed with respondent that glucagon raises blood sugar and counters the effect of insulin, which lowers blood sugar. In his opinion, however, SVT's slightly elevated glucagon level is not relevant to her diagnosis. Glucagon experts have recognized that patients with type 2 diabetes can have a high glucagon level. It is not reasonable to assume that SVT's glucagon level was a response to a recent hypoglycemic episode. This is not a widely-held belief.

In Dr. Jaffe's opinion, it is not reasonable to assume that SVT's elevated insulin represented an overproduction of insulin by her pancreas. Insulin resistance is characterized by a normal or a high insulin level coupled with elevated blood sugar levels. He explained that the "universal teaching on this would be that an elevated insulin level in someone with an elevated blood sugar demonstrates insulin resistance," meaning that it is not producing the typical blood sugar lowering effects. The elevated insulin "documents that this patient has insufficient insulin to control her blood sugar." Dr. Jaffe agreed with respondent that insulin resistance is not something that can be proven by looking at a slide under a microscope. Rather, it is determined by blood chemistry tests interpreted based on the standard of care in the community. This concept is well-established in the peer-reviewed literature; there is no debate. SVT's insulin resistance is established by a normal or a high insulin level and elevated blood sugar levels as confirmed by her February 4, 2014 test results.

43. In Dr. Jaffe's opinion, there was no justification for respondent to withdraw SVT's diabetes diagnosis in 2014, in light of her past history and then-current presentation. In January 2014, SVT had high blood sugar while being treated with diabetic medications to lower her blood sugar. Her diabetes diagnosis was further confirmed in the February 4, 2014 lab test results. To "de-diagnose" type 2 diabetes, the typical protocol would be to slowly reduce the patient's medications and verify that she continued to have normal blood sugars without them, preferably by an A1C test. Dr. Jaffe clarified that, even though respondent

[10] Insulin resistance can be caused by various conditions, including pregnancy and type 2 diabetes.

eliminated SVT's diabetes diagnosis in 2014, he continued to give her appropriate medications to treat diabetes. In his view, it was "unorthodox" for respondent to instruct SVT to avoid clear water for hydration and to use Gatorade. SVT had extreme hyperglycemia, so decreasing her sugar intake and starting insulin or other diabetic medication would have been appropriate.

44. *Hypoglycemia*: An elevated insulin level or C-Peptide level in the setting of laboratory-documented low blood sugars, of less than 50 or 55, while not on any medicine to lower blood sugar, is a hypoglycemic (low blood sugar) syndrome. This condition, when further evaluated, can result in a diagnosis of nesidioblastosis. Low blood sugar reactions are generally mild, causing a feeling of hunger, sweatiness, and mild confusion. In severe cases, there can be shaking, loss of consciousness, seizure or coma. In response to respondent's question, Dr. Jaffe testified that high insulin levels and high C-Peptides can be seen in patients with insulinoma tumors; however, this is only if those patients also have a laboratory-documented low blood sugar of less than 55. Once the low blood sugar is documented by the laboratory, it is appropriate to perform tests, including C-Peptide and insulin, to determine if the patient has tumors, including cells that make too much insulin called nesidioblastosis. It is not appropriate to proceed on the assumption that the blood sugar is low based upon a hypothesized rebound effect (e.g., Somogyi rebound).

Respondent uses non-contrast brain MRIs to find evidence of hypoglycemia when it is difficult to document low blood sugars. Dr. Jaffe testified that he is aware recurrent hypoglycemia produces abnormalities on non-contrast brain MRIs; however, individuals with low blood sugar can have totally normal brain MRIs, and people without low blood sugar can have abnormal MRIs. An abnormal non-contrast brain MRI does not establish that a person has low blood sugar. The standard of care in California to diagnose a hypoglycemic disorder is to test the patient's blood sugar in a certified clinical laboratory.

45. *Nesidioblastosis*: Nesidioblastosis is one subset of disorders of low blood sugar. It occurs when the pancreas's insulin-producing cells make too much insulin and cannot reduce the amount of insulin. This condition is very unusual. It can be seen in babies with very low blood sugar, whose insulin measure is high, and in some adults after bariatric surgery. In both instances, these patients with hypoglycemia were not taking any medications to lower their blood sugar.

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46. In Dr. Jaffe's opinion, there was no justification for respondent to diagnose SVT with nesidioblastosis. SVT's high insulin levels on the February 4, 2014 glucose tolerance test are not consistent with an insulin-secreting tumor, because such tumors are characterized by hypoglycemia, low blood sugar, and SVT did not have low blood sugar. The diagnosis of nesidioblastosis is reserved for patients who have hypoglycemic syndromes while not taking medications to lower the blood sugar. SVT had the opposite condition: diabetes characterized by hyperglycemia for which she took multiple medications. Respondent's diagnosis was confusing because there "is no low blood sugar documented here in the clinical lab for the clinical syndrome of hypoglycemia caused by nesidioblastosis." It was not demonstrated that SVT had a hypoglycemic syndrome after she

was taken off medications to treat high blood sugar. This is what the standard of care requires.

47. Dr. Jaffe is familiar with the Somogyi rebound, in which a patient can have a high blood sugar following a low blood sugar.[11] He explained that the presence of the Somogyi rebound is debated; it is an "old theory" subject to considerable controversy. There is a belief that it is primarily the effect of peaking of insulin action; the duration of the hypoglycemia is also variable. In Dr. Jaffe's opinion, the degree of SVT's hyperglycemia is not possible from a Somogyi rebound; her case is one of persistent extremely elevated hyperglycemia.

48. In support of his opinions, Dr. Jaffe provided articles and textbook chapters from peer-reviewed journal articles pertaining to the diagnosis of diabetes, hypoglycemia, and nesidioblastosis, authored by experts in glucose disorders and metabolism. He also provided copies of articles for which respondent only provided abstracts and he reviewed excerpts from respondent's self-published book "Disorders of Blood Sugar: The Illa Protocol," including chapters on: "*Turning ADA on its Head: a Conceptual Preview of the Illa Protocol*," and "*The Illa Protocol: A Systematic and Safe Method of Controlling Diabetes Mellitus While Avoiding Hypoglycemia*." This book was not peer-reviewed. In Dr. Jaffe's opinion, respondent's protocol does not even reflect a minority opinion among experts; it is simply respondent's opinion.

49. Dr. Jaffe testified that, considered collectively, respondent's new diagnosis of nesidioblastosis, coupled with his withdrawal of SVT's diagnosis of type 2 diabetes, was an extreme departure from the standard of care, in light of her long history of diabetes and her presentation in 2014 in a much worse condition.[12] SVT needed a diabetes expert to recognize and care for her diabetes, by either changing her medications or having a discussion about insulin, because "many, if not most, patients with type 2 diabetes end up on insulin." Instead, respondent inappropriately postulated and documented that SVT had a very unusual disorder characterized by low blood sugars while not taking any diabetic medications. In Dr. Jaffe's opinion, it was an extreme departure to remove a diagnosis of a condition SVT actually had and to consider and test for a condition she probably did not have, especially where the tests ordered then confirmed that she had type 2 diabetes. This is not within the standard of care for a physician holding himself out as a diabetes specialist. Such physician should be held to the standard of physicians who are endocrinologists and certified in diabetes endocrinology metabolism, who understand the complex relationships between blood sugar and insulin, and high and low blood sugar disorders.

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[11] This concept derives from Dr. Michael Somogyi's 1959 abstract from the American Journal of Medicine, entitled "Diabetogenic effect of hyperinsulinism."

[12] As reflected in Dr. Jaffe's Report, he considered each act individually (withdrawing the diabetes diagnosis and diagnosing nesidioblastosis, while having test results which confirm diabetes) to be a simple departure.

50. *Testing and Documentation*: Respondent's progress notes for SVT contained a single A1C test from May 12, 2008, which was repeated in other notes. The A1C should be measured or documented in the record, if performed elsewhere, every three-to six months. There were no documented creatinine levels or kidney labs. After an initial foot examination in 2008, respondent did not document any annual foot examinations. In Dr. Jaffe's opinion, because respondent held himself out as a blood sugar specialist, he was obligated to ensure that SVT received the tests required by the standard of care, either personally, or from another source, and to document that in the medical record. Based on his review, Dr. Jaffe concluded that, from January 2011 through 2014, respondent failed: (1) to order or document any new A1C test or results; (2) to complete a sensory foot examination, at least annually, or to document that examination (especially because SVT complained of neuropathic pain); and (3) to test SVT's lipid levels and urine micro albumin (for kidney damage) at least annually, or document that being done elsewhere. These are simple departures from the standard of care.

B. David Lewis Geffner, M.D.[13]

51. Dr. Geffner obtained his medical degree in 1967 from Georgetown University School of Medicine. He then became licensed in both New York (1968) and California (1969). He interned at the Brooklyn Veterans' Administration (VA) Hospital, and completed his residency in internal medicine at Cornell Cooperating Hospitals (New York, Memorial and Sloan-Kettering Hospitals). Dr. Geffner completed a Research Fellowship in Endocrinology at the New York Hospital (1971-1972), followed by a research fellowship in endocrinology at UCLA/Wadsworth VA Medical Center (1972 -1973). Dr. Geffner is certified by the ABIM and ABIM-certified in Endocrinology, Diabetes and Metabolism.

Since 2013, Dr. Geffner has been a Professor of Medicine in the Division of Endocrinology, Diabetes and Hypertension at UCLA's David Geffen School of Medicine, with previous appointments in this Division beginning in 2008. These positions encompassed clinical, teaching and academic components. He has lectured and published peer-reviewed papers in numerous areas, including diabetes. From 1974-2000, Dr. Geffner was the Chief of Endocrinology at Kaiser Permanente Medical Group. Other past academic appointments include work as a Teaching Affiliate at Cedars-Sinai Medical Center. Dr. Geffner is the past president of the America Board of Quality Assurance and Utilization Review Physicians, and the past president of the Los Angeles chapter of the American Diabetes Association. He has served as an expert reviewer for Molina Healthplans, for the Center for Health Dispute Resolution (Maximus), and for the Medical Board. He has reviewed 20 cases for the Board, and found no physician violations in 30 percent of these cases.

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[13] Dr. Geffner wrote his report in 2015, before his recent diagnosis with a medical condition, a symptom of which is expressive aphasia. He explained that this condition was not manifest at the time he wrote his report, did not affect his ability to formulate his opinion, and currently only affects his ability to express his opinion.

52. In his November 10, and December 12, 2015 Reports, Dr. Geffner opined that respondent engaged in extreme departures from the standard of care: (1) by failing to maintain accurate medical records (e.g., frequently repeating his initial note verbatim; failing to document a foot exam); (2) by failing to make appropriate tests and referrals (e.g., to have an A1C to assess blood sugar control and urine micro albumen/creatinine to assess kidney function every three to six months, and an annual cholesterol (lipid) test; (3) by making inappropriate tests or referrals (e.g., doing a glucose tolerance test, which is unnecessary in a patient like SVT with significant hyperglycemia; and recommending an MRI of the brain).

53. In Dr. Geffner's opinion, respondent's withdrawal of SVT's type 2 diabetes diagnosis and substitution of a diagnosis for nesidioblastosis, without documented hypoglycemia, constituted an extreme departure from the standard of care. He testified that, based on his review of respondent's February 10, 2014 progress note, SVT's February 4, 2014 lab results are consistent with a diagnosis of type 2 diabetes. SVT had glucose levels over 200 at fasting (348), half-hour (449), one-hour (457), two-hour (418), three-hour (379) and four-hour (350) intervals. Dr. Geffner described the relationship between nesidioblastosis as a diagnosis and hypoglycemia as a clinical syndrome. Nesidioblastosis might be among the various causes of hypoglycemia; however, it is a very rare situation, which is apparent in neonates and in patients with gastric bypass surgery. Dr. Geffner was not aware that UC Davis's Department of Surgery has a nesidioblastosis clinic or that respondent has referred patients to it for further work up. In his review of respondent's medical records for SVT, Dr. Geffner saw no documented lab results that showed SVT had low blood sugar, as opposed to high blood sugar. Throughout her treatment by respondent, SVT was on oral medication to try to lower her blood sugar.

54. Because he held himself out as a diabetic expert, suggesting an expertise beyond that of internal medicine, respondent was required to perform or document certain tests and/or referrals recommended by the American Diabetes Association. In Dr. Geffner's opinion, considered collectively, respondent engaged in the following extreme departures from the standard of care for treating a diabetic patient:

a. Failure to document a sensory foot examination after April 28, 2008. In his first progress note, respondent documented a sensory foot exam for SVT, indicating light touch intact on both feet; however, there was no evaluation of her peripheral pulses (dorsalis pedis pulses) and no 10-gram filament touch. There was no other foot exam documented in SVT's chart. This was particularly concerning because SVT complained of neuropathy. Every diabetic requires periodic foot examinations, every three to six months, to check for diabetic peripheral neuropathy and potential lesions. This is particularly important in a patient, like SVT, who has complained about pain and neuropathy in her feet.

b. Failure to obtain and document A1C tests after April 28, 2008. The standard of care requires periodic A1C tests because the results direct appropriate treatment. Respondent only obtained and documented one A1C lab result for SVT on April 29, 2008, which he then reiterated in his subsequent progress notes.

c. Failure to obtain and document tests for SVT's lipid levels and her urinary micro albumin creatinine ratios for kidneys. Due to the potential for kidney failure, it is important to check for early kidney problems for patients with type 2 diabetes.

RESPONDENT'S EVIDENCE

A. Respondent's Testimony

55. Respondent received his medical degree from Stanford University Medical School in 1971, and completed his internship at Kaiser Foundation Hospital in San Francisco in 1972. In June 1974, respondent completed a fellowship in clinical pharmacology at Stanford. He completed his first year of residency at UCLA School of Medicine in June 1975, while working as an emergency room (ER) and on-call doctor at Kaiser. In June 1976, he completed his second year of residency at a UCLA-affiliated program at Sepulveda. Respondent then took and passed his board examination in internal medicine, becoming ABIM-certified for life.

Respondent's only additional training in the diagnosis, evaluation and management of hypoglycemic disorders is from his reading and experience. His only additional training in the diagnosis, evaluation and management of diabetes is from his annual continuing medical education (CME) courses and yearly diabetes conferences. Respondent has never held himself out as an endocrinologist. He relied heavily on endocrinologists in his practice and referred patients out to them as necessary. In 2009 and 2011, respondent was awarded expert reviewer certificates from the Board; however, this did not entail any special training and he has never been called upon to do any reviews for the Board. In 2012, at the request of the University of Gottingen in Germany, respondent gave a talk on dementia as related to blood sugar disorders.

56. From 1975 through 1987, respondent worked as an ER physician at hospitals in the Bay Area. From 1979 through 1988, he was in private practice with a large internal medicine group, with in-patient and out-patient responsibilities. From approximately 1988 through 2001, respondent's employment changed frequently and he moved positions almost every year. He explained that this occurred during the time when many facilities began replacing physicians with nurse practitioners and PAs. In addition, after his divorce, respondent moved to facilitate his son's education and found jobs as he could.[14] In 2001, respondent relocated to Northern California and worked at Sierra Vista State Hospital and for Sacramento Family Medical Group. From 2002 through 2007, respondent worked for Del Norte Clinics (Ampla Health), in Chico, Oroville and Lindhurst.

[14] Respondent's positions included: flight surgeon (1990-1991); Medical Director for Northern Valley Indian Health in Oroville and Intermountain Community Services in Berry Creek (1991-1992); ER physician at Biggs-Gridley Hospital (1993); outpatient physician at Sutter County Primary Care Clinic (1993-1994); locum tenens, Los Angeles (1994-1995); and hospitalist, medical director, urgent care physician and other temporary positions in various facilities in Southern California (1995-2001).

57. In 2007, respondent opened a private practice specializing in disorders of blood sugar in Chico. Respondent's publications include four editions of his book, "Disorders of Blood Sugar: The Illa Protocol" (2007, 2008, 2009 and 2012), which focuses on common and rare disorders of blood sugar. Respondent has also studied computers and computer software.

While in private practice, respondent developed an automated patient interviewing system in eight languages. He did this in conjunction with Stanley Lieberson, Ph.D., a clinical psychologist with expertise in computers, who worked with respondent as an independent contractor for many years. Respondent had Dr. Lieberson program his electronic medical records (EMR) in ways he can juxtapose old and new data to help him analyze trends. During patient visits, respondent typically pulls forward his initial note and updates the note during the new appointment. While this might be criticized, respondent maintains the SOAP format. He can push a button on the EMR and pull up data in the patient's medical record that is not included in the progress note. Respondent's practice was to have his patients bring their home glucose meters with them for their appointments. His office staff downloaded the readings and Dr. Lieberson transferred it to the database where it was available for respondent's review. Respondent provided periodic Accu-Chek Trend Reports/Trendgraphs for SVT from April 28, 2008, through February 10, 2014, and Dexcom reports for March 3, through 9, 2014. He noted that the Dexcom CGM is FDA-approved and characterized it as "highly accurate," even though it measures interstitial fluid rather than blood. In respondent's opinion, this is the best CGM available.

58. Respondent closed his practice in August 2016. Since that time, he has worked at Paradise Immediate Care and at the Veteran's Administration (VA) in Colorado. Since September 15, 2016, respondent has been Vet Pro Qualified to work in any VA hospital in the United States. He has not worked since May 2017, and attributes this to the negative effects of the Accusation posted on the Board's web site. Respondent is 72 years old. He was diagnosed with type 2 diabetes 18 years ago and is insulin-dependent.

59. In 2010 or 2011, respondent learned about nesidioblastosis from a patient who had vacillating blood sugars that were very difficult to control. The patient gave respondent a paper about nesidioblastosis which changed his thinking and was the impetus for his investigation into this disease. From 2008 to 2010, respondent had no patients diagnosed with nesidioblastosis. In the years since, the number of patients respondent has identified with hypoglycemia and/or nesidioblastosis increased. In 2014, approximately 25 to 30 percent of his patients had a diagnosis of nesidioblastosis. This amounted to 350 patients, approximately half of whom were tested with low blood sugars in a laboratory.[15]

[15] To help explain his analysis during the hearing, respondent provided exemplars of patients he has diagnosed with nesidioblastosis. Only one of the exemplar patients had a low blood sugar under 55 documented in a laboratory; the blood sugar in the remaining patients was determined based on readings from CGMs.

60. Respondent relies on principles enunciated by Philip Cryer, M.D., who he described as the ADA's hypoglycemia expert. According to respondent, Dr. Cryer pointed out the phenomenon of "hypoglycemia unawareness" when a patient's blood sugar goes below 55. This constitutes neuroglycopenia, meaning that hypoglycemia is causing nerve damage to the central nervous system and autonomic nervous system. After three-to-four severe episodes of hypoglycemia, a patient can lose the ability to detect signs of early hypoglycemia (trembling, sweating). Once this occurs, the patient begins to show damage to brain cells, including loss of ability to concentrate and dizziness; ultimately, the low blood sugar can cause seizures, coma and death.

61. Motivated by Dr. Cryer's conclusions, respondent began investigating his type 2 diabetes patients who were having concerning symptoms. He began to look at their glucagon, C-Peptide and insulin levels. He also began to incorporate non-contrast brain MRIs into his evaluation protocol after learning that permanent brain damage visible on an MRI can occur when a patient's blood sugar drops for even a relatively short period of time.

Working with Dr. Lieberson, respondent prepared a chart entitled "Overall Clinical Characteristics of the Endogenous Hyperinsulinism [EH] Populations (includes Nesidioblastosis)." This chart lists symptoms reported by 197 patients with EH, which he categorized as: neurological (short term memory loss, balance problems, tremors, headaches, dizziness, blurred vision, syncope, epilepsy); psychological (loss of focus, depression, anxiety, emotional outbursts, disorientation); and somatic (weight gain, hypertension, weakness, tachycardia, and dysrhythmia). Respondent looks at a cluster of these symptoms and tries to correlate them to discover whether a pattern exists in patients with EH. He agreed that, individually, these symptoms could be caused by a number of medical conditions and/or by a patient's medications.

62. Respondent disputed SVT's testimony that he yelled at her when she returned to his care in 2014. He does not yell at patients. SVT was very sick and he was concerned she might come to harm. Respondent tried to readjust her medications to keep her blood sugar down but this proved to be difficult. He encouraged SVT to buy his book because there are no other texts which outline the details of nesidioblastosis; he has not realized any significant financial gains from its sale. Due to the general unfamiliarity and lack of understanding about nesidioblastosis in the Chico area, respondent understood why SVT may have been upset by this diagnosis.

63. Respondent characterized SVT as a very difficult case. She was obese, a weekend alcoholic, and on medications that can increase blood sugar. Respondent was very concerned by her alarming new symptoms, and particularly her report of one week of dizziness. She also had many years of treatment for depression and mood disorders, and had experienced memory loss before she was prescribed Topamax; these are among the symptoms experienced by respondent's patients with nesidioblastosis. Respondent believed SVT's presentation in January 2014, to be "dreadfully wrong and different," and that she was transitioning from type 2 diabetes to nesidioblastosis. He believed it was incumbent on him to investigate her condition, which he did. Respondent characterized his recommendation

that SVT drink Gatorade instead of water as a valid strategy. Gatorade has "so little sugar" and contains electrolytes, which are particularly important in hot environments where there is a loss of sodium. His office tracked patients who ate sugar and drank Gatorade and found no change in blood sugar measured on CGM.[16]

64. The Kuroda protocol is a testing format for nesidioblastosis developed by Dr. Kuroda in Japan and used internationally, which assays for insulin and C-Peptide. Respondent modified Dr. Kuroda's protocol by adding a test for glucagon, which is a fairly reliable indicator of hypoglycemia, especially if it is low. Glucagon is a counter-regulatory hormone that only occurs after hypoglycemia. Elevated glucagon is an indirect means of establishing hypoglycemia. This is the test respondent ordered for SVT. Respondent characterized the modified Kuroda protocol as a much more efficient and sensitive means of detecting hypoglycemia and hyperinsulinism.[17]

65. Respondent explained that the Somogyi rebound can be very fast and becomes worse the more damage a patient has. In young patients like SVT, very fast periodic fluctuations occur, with hypoglycemic episodes lasting as little as two-to-three minutes, followed by sharp rebounds out of low blood sugar range. The Dexcom is an average of five one-minute readings. As a result, it was not possible to see SVT's very fine Somogyi rebounds; all that is shown is high glucose. SVT's Dexcom reading did not go very low (e.g., her lowest blood sugar reading was above 250 and her highest was 400). Respondent realized he needed another way to document her hypoglycemia.

66. Respondent found SVT's hypoglycemia to be documented in her February 4, 2014, modified Kuroda glucose tolerance lab results, which showed high glucagon levels, meaning that her pancreas was overactive. This was confirmed by her December 5, 2013 C-Peptide test, which had risen from a 6.6 to an "alarming" level of 7.89, at the same time that her estimated glomerular filtration rate (eGFR 110) showed normal kidney function. This C-Peptide, viewed together with the recent lab results, demonstrated to respondent that SVT was "massively overproducing insulin in a random fashion" and "over time will lose brain tissue." Although SVT did not have low blood sugar demonstrated in a clinical laboratory to document hypoglycemia, in respondent's opinion, this test provides a reliable "indirect measure" of her low blood sugar. Based on these results, respondent believed that SVT "over time will go on to deteriorate, have memory loss, have emotional problems" and experience other symptoms he has found common in such patients. In respondent's opinion,

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[16] In its closing brief, complainant requested official notice that: "Glaceau Smart Water has been on the market since 2007 and it contains no sugar, but has electrolytes, whereas Gatorade has 56 grams of sugar in a 32 ounce bottle." This request does not comport with Government Code section 11515 and is denied.

[17] In 2012 or 2013, respondent negotiated with Quest Labs, over a period of months, to establish a modified Kuroda lab test with appropriate standards and protocols. This is the test he used with SVT.

it behooves physicians to use data from the Dexcom CGM and non-contrast brain MRIs for complicated patients like SVT and to consider less common diseases.

67. In respondent's opinion, SVT's 2014 tests did not demonstrate that she had type 2 diabetes. The Dexcom technology shows that a patient's glucose level is rapidly fluctuating all the time and the Somogyi rebound phenomenon can be very fast. This is why, in young patients like SVT, respondent has used the indirect measure of glucagon to document the hypoglycemia. SVT had high C-Peptides and high insulin, which are "almost incontrovertible evidence of overproduction of insulin by her pancreas, which is never found in type 2 diabetes." Respondent agreed that he did not do any tests on SVT that showed her blood sugar to be under 60, and he ordered no clinical labs on SVT that showed blood sugar under 55. In respondent's opinion, it was "highly irrelevant" that the patients with nesidioblastosis cited in peer-reviewed literature were completely off of their diabetic medications and had clinically documented low blood sugars, unlike SVT. Similarly, he thought it irrelevant that the two patients relied upon in the Kuroda protocols had documented low blood sugars, unlike SVT.

68. Respondent agreed that the peer-reviewed literature from 1975 to 2006 found fewer than 100 adults to have nesidioblastosis. He has identified 300 to 350 patients in Chico with nesidioblastosis. In respondent's opinion, his office was able to diagnose these patients by using the latest technology, and by looking at patients' glucagon and C-Peptide levels. His office computer gives him the data about how many such patients there are. The experts in the peer-reviewed literature did not use these techniques. By contrast, his conclusions are based on data, and not just on a theory. Respondent acknowledged that he is the only person doing this protocol in the State of California; that his is "an opinion of one." When asked for the scientific basis for relying on his theory, respondent provided examples in history of doctors who were mocked and shunned based upon their new ideas, which are now well-recognized in the scientific community.

69. Respondent emphasized that he has referred patients with nesidioblastosis to two professors at UC Davis's Department of Surgery, Pediatric Surgery: Shinjiro Hirose, M.D., Chief of Pediatric Surgery, and Richard Bold, M.D. When respondent suspects nesidioblastosis, he does preliminary testing (modified Kuroda protocol, brain MRI). He then asks the patient if they would like to go to UC for "possible surgery, confirmatory treatment." Respondent did not get to this point with SVT because her insurance denied the brain MRI and she became suspicious of his diagnosis. Had SVT remained in his care, respondent would have referred her to a specialist clinic for confirmation.[18]

70. In response to Dr. Jaffe's and Dr. Geffner's concern for his patients' safety, respondent asserted they have no experience with nesidioblastosis and are not using modern

[18] In his Board interview, respondent acknowledged that, if SVT had followed his recommended management plan, she would have had very high glucose levels "for a while, but the glucose levels I said were Somogyi rebounds . . . they pop up after they have a low, pop up after a low, because she's having a random release."

techniques to detect it. "If you do not test for it, you will never see it." Respondent believes insulin resistance is more akin to a religious belief rather than part of a description of what constitutes type 2 diabetes. He believes it to be a theory which is unsubstantiated by tissue, imaging and/or biopsy evidence, and which must be accepted and adhered to without question (like the now-discredited theory that the earth is flat) for professional advancement. Respondent analogized himself to the child in the *Emperor's New Clothes*, who alone sees that the emperor is naked. In his opinion, it is illegal for the Board to penalize him for his opinions and new ideas, based on his critical review of data; rather, he is entitled to protection for advocating for more sensitive testing. He also believes that, if SVT had understood that nesidioblastosis is a real diagnosis, which is treated by clinics at UC Davis, she might have been less worried about him and not complained. Respondent has treated over 48,000 patients in 46 years. Since he closed his office, there are no diabetes specialists at any level in Butte County, for a population of 23,000. He has had no prior disciplinary history with the Board.

71. Respondent emphasized that he was not SVT's primary care physician during his treatment and that routine tests relating to diabetes should have been performed or ordered by her primary treatment providers at Ampla Health. He also provided the following explanations for not ordering certain tests as alleged in the Amended Accusation.

a. Hemoglobin A1C: Respondent admits that the only A1C he ordered for SVT was on April 29, 2008. His failure to regularly order the A1C is an indication of his hypervigilance, rather than his negligence. Because the A1C is a 90-day average and can be misleading, he chooses the more sensitive method of following the patient's home glucose meter readings. These meters provide patients multiple readings a day, and give respondent a better understanding of their sugar control. Respondent will order an occasional A1C, but it is not helpful to him in long-term patient management.

Respondent is not aware of any other practitioners who do not perform A1C tests and rely solely on home glucose monitoring tests. In his opinion, he did not violate the standard of care because he was following SVT in a different and more sensitive way by having her routinely download her home glucose readings. As stipulated by the parties at hearing, the ADA's "Standard of Care recommendations are not intended to preclude clinical judgment."

b. Foot exams: Respondent typically focuses on the patient's specific complaint. After his initial foot examination in 2008, respondent did not believe it was his role to follow up with SVT's annual foot examinations.

c. Urine Micro Albumen/Creatinine Tests: Respondent did not regularly order serum urine micro albumen tests to determine SVT's kidney function, and he disputes that the standard of care requires this test. In his 46 years of experience, respondent has not found this urine test to be reliable at all. It simply shows damage or no damage. While this urine test is useful for showing early kidney damage, if a patient's kidney function changes, either improving or deteriorating, it is not reflected. Respondent prefers the eGFR blood test because it is more sensitive and provides the physician a more immediate indication of

kidney damage. For long-term patient management, the eGFR is a more sensitive test and he is allowed to use his clinical judgment to do this rather than to rotely follow the guidelines.

d. Lipid Testing: Respondent agreed that the ADA recommends lipid panels be done for diabetics. He did not do any lipid testing on SVT at any time. He explained that, once blood sugar is successfully controlled, lipid problems are eliminated. From 2008 through 2011, SVT's blood sugar was controlled and she was being seen by her primary care person at Ampla Clinic. He did not communicate with any providers at Ampla about this issue and did not believe it necessary to order the panel. When SVT returned to his care in 2014 with very high blood sugars, respondent did not order a lipid panel because he "felt she had nesidioblastosis, and that she was in danger, and that I was very alarmed." He prioritized lowering her blood sugar and investigating the cause of her Somogyi rebounds.

72. Respondent does not believe he violated the standard of care in treating and diagnosing SVT and believes the Amended Accusation should be dismissed. If discipline is determined to be appropriate, respondent is willing to take CME classes as a condition of probation. However, he is not willing to be "brainwashed" or trained under people "like Dr. Jaffe who only believe in type 2 diabetes and mythical insulin resistance," until he complies and "is broken." Respondent is not willing to repudiate who he is and what he has done as his life's work. He is willing to dialogue with other professionals and he is open to modification of his ideas if someone will talk to him, rather than try to punish him.

B. Testimony and Recommendations in Support of Respondent

73. Dr. Lieberson testified about his work developing and enhancing respondent's EMR. He demonstrated its multiple data functions, which were more detailed than the information provided in the progress notes when viewed alone.

74. Three of respondent's former patients testified on his behalf, and provided positive commendations of his caring and successful treatment of their conditions.

a. Patient TCC was first diagnosed with type 2 diabetes in 1967, and was on medications for three years. He became very ill in 1993, and was again placed back on diabetic medications. He had several strokes in 2012. His family doctor suggested he see respondent, who he described as an "outside the box" diabetes expert. TCC began seeing respondent in March 2013. After additional blood testing, respondent diagnosed TCC with nesidioblastosis. He discontinued some of TCC's medications and prescribed new ones, including glucagon shots. TCC was originally on seven glucagon shots a day; he now has three to five shots a month. TCC has done much better on medications respondent prescribed.

b. MS is a health worker who experienced dizziness and weight loss her doctors could not explain. After she had exhausted all other doctors, her primary care doctor suggested she go to see respondent, who he described as "a quack." Respondent listened to her non-judgmentally, ordered testing, and eventually diagnosed her with nesidioblastosis. A

lesion on her brain was discovered by a brain scan. MS explained that the difference in her life is profound due to the treatment she received from respondent. Since respondent closed his office, MS is seeing another doctor who is "unwillingly" treating her in the same manner as respondent did. MS was never treated for diabetes.

c. KE is type 2 diabetic, who was diagnosed with kidney problems. Respondent was the first doctor in his life who spent over two hours with him reviewing his history, tests and course of treatment. Respondent changed his medications. Currently, KE is not on dialysis and his blood sugar is under control. Respondent also helped him with a cardiac condition. He considers respondent to be a "fantastic" doctor.

75. Respondent submitted seven letters of support from former patients (Exhibit F.) He explained that many were written by patients who were initially diagnosed as type 2 diabetic patients, who he then diagnosed and treated for nesidioblastosis. These patients indicated: that respondent helped them more than any other doctor did; that "sometimes we need mavericks;" that respondent was "always polite and professional;" that respondent "absolutely saved my life," was extremely knowledgeable and passionate about what he does and explains things well; and is a physician who "always checks my feet." Each former patient indicated improved health conditions following treatment by respondent.

Discussion[19]

76. It is well settled that the standard of care for physicians is the reasonable degree of skill, knowledge and care ordinarily possessed and exercised by members of the medical profession under similar circumstances." (*Avivi v. Centro Medico Urgente Medical Center* (2008) 159 Cal.App.4th 463, 470; *Brown v. Colm* (1974) 11 Cal.3d 639, 643.) A medical professional is held to the standard of care in his or her own "school" or specialty. As a physician who holds himself out as an expert in diabetes and blood sugar disorders, respondent is held to that standard of learning and skill normally possessed by physicians who understand the complex relationship between blood sugar and insulin, and high and low blood sugar disorders.

77. Dr. Jaffe and Dr. Geffner are ABIM-certified in endocrinology, diabetes and metabolism, a subspecialty beyond their general ABIM certifications. Each of these experts is well-qualified in the standards of care in California for physicians who hold themselves out as experts in diabetes and blood sugar disorders. Both physicians have diagnosed and

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[19] Dr. Jaffe and Dr. Geffner offered opinions on respondent's failure to refer SVT for an ophthalmological evaluation; however, this was not alleged as cause for discipline in the Amended Accusation and there was no request to amend the Amended Accusation to conform to proof. Dr. Geffner also expressed opinions on other perceived deviations from the standard of care which were not alleged (e.g., failure to counsel SVT regarding need for weight loss, to consider insulin to control her hyperglycemia; and to place SVT on medications to decrease risk of heart attack or stroke and to protect her kidneys and eyes.) Accordingly, no findings or conclusions are made on these opinions.

treated patients with diabetes, hypoglycemia and nesidioblastosis. Both have had significant involvement in academia and in conducting quality of care reviews in these areas of specialization.

By contrast, respondent is ABIM-certified for life, but is not ABIM- certified in endocrinology, diabetes and metabolism. Respondent concedes that his protocol and opinions are not generally accepted as reliable in the medical community and are not even considered minority opinions. As complainant accurately notes, evidence based on a new scientific method is admissible only on a showing that the method has been generally accepted as reliable in the scientific community. (*People v. Kelly* (1976) 17 Cal.3d 24, and *Frye v. United States* (D.C. Cir. 1923) 293 F. 1013.) Accordingly, respondent's opinions are not given any significant weight. The opinions of Dr. Jaffe and Dr. Geffner, individually and collectively, are entitled to substantially greater weight than those of respondent. Their testimony persuasively established that respondent violated the standards of care in his treatment of SVT, as discussed below.

78. It was established by clear and convincing evidence that respondent engaged in a departure from the standard of care by withdrawing SVT's type 2 diabetes diagnosis during the months he treated her in 2014. As explained by Dr. Jaffe and Dr. Geffner, and as demonstrated by respondent's 2014 progress notes and SVT's February 4, 2014 lab results, SVT met the diagnostic criteria for type 2 diabetes throughout the time in 2014 that respondent treated her. (Factual Findings 41 and 53.)

Both Dr. Jaffe and Dr. Geffner strongly disagreed with respondent's written statement that: "insulin resistance is more akin to a religious belief or belief in alien abduction or creationism." Both experts characterized this statement "unbelievable." Dr. Jaffe explained that it is not supported by any peer-reviewed scientific literature discussing the standards of care for diabetes and diabetes experts. It is not reflective of even a minority opinion in the scientific and medical community. Because type 2 diabetes "is a disorder characterized by insulin resistance," this statement caused Dr. Jaffe to question respondent's ability to properly diagnose diabetic patients. Similarly, based on this statement, Dr. Geffner had strong concerns about respondent's overall judgment and ability to treat patients, because SVT's "hyperglycemia is obvious. The need to treat hyperglycemia to bring it down is apparent."

79. It was established by clear and convincing evidence that respondent engaged in a departure from the standard of care by failing to adequately document a basis for SVT's alleged hypoglycemia when she returned to his care in 2014. Both Dr. Jaffe and Dr. Geffner agreed that the standard of care requires that low blood sugar under 55 must be established in a certified clinical laboratory before the diagnosis of hypoglycemia or nesidioblastosis can be made. Respondent conceded he did not document her low blood sugar in this manner. Further, Dr. Jaffe and Dr. Geffner agreed that respondent inappropriately applied the modified Kuroda protocol to a patient with very high blood sugar. The Kuroda study on which respondent relied for his testing protocol involved two patients, both of whom had documented hypoglycemia of under 50 and 62 mg/dL. By contrast, SVT had no documented

low blood sugar and had a vastly different clinical presentation of extreme hyperglycemia. The CGM readings are not a reliable substitute, and the hypothesized Somogyi rebounds perpetuated respondent's result-driven analysis of SVT's test results. Little weight is given to respondent's "indirect" method of establishing SVT's low blood sugar. This technique is not recognized in the medical community as comporting with the standard of care.

80. It was established by clear and convincing evidence that respondent engaged in a departure from the standard of care by diagnosing SVT with nesidioblastosis when she returned to his care in 2014. Dr. Jaffe and Dr. Geffner agreed that in patients with hyperglycemia like SVT it is not relevant whether their insulin levels or their glucagon levels are high or low. Dr. Geffner agreed with respondent that glucagon is released in response to hypoglycemia; however, in his opinion, it is not reasonable to diagnose nesidioblastosis or an insulinoma where a patient like SVT has blood sugar levels that have been persistently documented to be hyperglycemic.

Both Dr. Jaffe and Dr. Geffner also agreed that the articles respondent relied on to demonstrate that former diabetic patients can later developed nesidioblastosis were not applicable to SVT. The patients in each of these articles had at least a two- to four-month period of being on no blood sugar lowering diabetic medications and, despite that, were having low blood sugar reactions. These articles were reflective of a completely different clinical scenario than that presented by SVT. Respondent's opinion to the contrary is not persuasive.

81. It was established by clear and convincing evidence that respondent engaged in repeated departures from the standard of care when he failed to conduct or document annual foot exams for SVT; and failed to order or document the following tests for SVT from January 2011 through March of 2014: hemoglobin A1C, urine micro albumen/creatinine tests, and tests of lipid levels. Complainant's motion to amend the Amended Accusation to conform to proof on this point is granted.

82. It was established by clear and convincing evidence that respondent engaged in a departure from the standard of care by failing to maintain adequate and complete records of his care and treatment of SVT from January 2011 through March 2014, as described in Factual Findings 50 and 54.

83. When all the evidence is considered, respondent's combined departures from the standard of care detailed Factual Findings 78, 79 and 80 constitute a single extreme departure from the standard of care. The departures detailed in Factual Findings 81 and 82 constitute repeated simple departures from the standard of care.

84. *Appropriate Discipline*: Respondent's firm belief in the accuracy of his intellectual conclusions, coupled with his frank disdain for established principles of type 2 diabetes, are concerning. However, in determining the appropriate level of discipline, respondent's departure from the standard of care by withdrawing SVT's type 2 diabetes diagnosis in 2014 must be considered in light of Dr. Jaffe's conclusion that respondent did

not violate the standard of care in his selection of appropriate diabetes treatment for SVT after he withdrew this diagnosis. (Factual Findings 32 and 43.) In addition, respondent's departure from the standard of care for evaluating hypoglycemia must be considered in light of Dr. Jaffe's conclusion that respondent met the standard of care "for treatment of suspected hypoglycemia in a person taking anti-hyperglycemic medications." (Factual Finding 34.)

85. Other positive or mitigating factors weighing in respondent's favor are: his 46-year licensure history with no prior discipline; the sincerity of his concern for the well-being of his patients, as reflected in SVT's testimony for the pre-2014 period and in the testimony of his former patients before and after that time; and in respondent's diligent efforts to understand and work with patients with difficult medical issues. Respondent's testimony was also persuasive that he did not attempt to foist his book on SVT for financial gain. When all the evidence is considered, the public interest will be protected by placing respondent on a period of probation, subject to the conditions outlined below.

LEGAL CONCLUSIONS

1. *Purpose of Physician Discipline*: The purpose of the Medical Practice Act is to assure the high quality of medical practice. (*Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 574.)

2. *Burden and Standard of Proof*: To revoke or suspend respondent's medical license, complainant must establish the allegations and violations alleged in the Amended Accusation by clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) The requirement to produce clear and convincing evidence is a heavy burden, far in excess of the preponderance of evidence standard that is sufficient in most civil litigation. Clear and convincing evidence requires a finding of high probability. The evidence must be so clear as to leave no substantial doubt. It must be sufficiently strong to command the unhesitating assent of every reasonable mind. (*Christian Research Institute v. Alnor* (2007) 148 Cal.App.4th 71, 84.)

3. Business and Professions Code section 2234 provides that the Board "shall take action against any licensee who is charged with unprofessional conduct," which includes gross negligence, and repeated negligent acts.

4. *Gross Negligence*: Under Business and Professions Code section 2234, subdivision (b), the Board may discipline a licensee's medical license for gross negligence. Gross negligence is defined as "the want of even scant care or an extreme departure from the ordinary standard of conduct." (*Cooper v. Board of Medical Examiners* (1975) 49 Cal.App.3d 931, 941; *Franz v. Board of Medical Quality Assurance* (1982) 31 Cal.3d 124, 138; *Gore v. Board of Medical Quality Assurance* (1980) 110 Cal.App.3d 184, 196.)

As set forth in the Factual Findings and Legal Conclusions as a whole and, particularly, in Factual Findings 76 through 80 and 83, complainant established by clear and convincing evidence that respondent was grossly negligent in his care and treatment of SVT based on his combined conduct of withdrawing the diabetes diagnosis and substituting a diagnosis for nesidioblastosis, without appropriately documented hypoglycemia. Legal cause is therefore established to discipline respondent's license on this basis.

5. *Repeated Negligent Acts*: Under Business and Professions Code section 2234, subdivision (c), the Board may discipline a licensee's medical license for "repeated negligent acts." To be repeated, there must be two or more negligent acts or omissions: an initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care. Negligence is conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm. A physician is required to exercise that degree of skill, knowledge, and care ordinarily possessed and exercised by other prudent physicians under similar circumstances. (*Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 998.)

As set forth in the Factual Findings and Legal Conclusions as a whole and, particularly in Factual Findings 81 and 83, complainant established by clear and convincing evidence that respondent engaged in repeated negligent acts in the care and treatment of SVT by failing to conduct or document annual foot exams; and to order or document hemoglobin A1C, urine micro albumen/creatinine, and lipid levels for SVT from January through March of 2014. Legal cause is therefore established to discipline respondent's license on this basis.

6. *Inadequate Medical Records*: Pursuant to Business and Professions Code section 2266, "[t]he failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct." As set forth in the Factual Findings and Legal Conclusions as a whole and, particularly, in Findings 50, 54, 82 and 83, complainant established by clear and convincing evidence that respondent failed to maintain adequate and accurate records for SVT from January 2011 through March of 2014. Legal cause is therefore established to discipline respondent's license on this basis.

7. *Motion to Dismiss*: Respondent contends that his professional opinion in the form of his nesidioblastosis diagnosis for SVT is protected from retaliation or discipline by Business and Professions Code sections 2056 and 2234.1 and that the Amended Accusation should be dismissed. As discussed below, these arguments are not persuasive and respondent's motions for summary judgment or to dismiss the Amended Accusation, and to remove the Amended Accusation from the Board's website are denied.

A. Advocacy for Medically Appropriate Health Care:

8. Business and Professions Code section 2056 declares that it "is the public policy of the State of California that a physician and surgeon be encouraged to advocate for medically appropriate health care for his or her patients." (Bus. & Prof. Code, § 2056, subd.

(b).) The phrase "to advocate for medically appropriate health care" is defined to mean, either: (1) "to appeal a payor's decision to deny payment for a service pursuant to the reasonable grievance or appeal procedure . . ."; or (2) "to protest a decision, policy, or practice that the physician, consistent with that degree of learning and skill ordinarily possessed by reputable physicians practicing according to the applicable legal standard of care, reasonably believes impairs the physician's ability to provide medically appropriate health care to his or her patients." (*Ibid.*) Penalizing a physician for the conduct protected by this statute is forbidden: "No person shall terminate, retaliate against, or otherwise penalize a physician and surgeon for that advocacy, nor shall any person prohibit, restrict, or in any way discourage a physician and surgeon from communicating to a patient information in furtherance of medically appropriate health care." (Bus. & Prof. Code, § 2056, subd. (c).)

9. As quoted above, the advocacy which is protected by this statute must be "consistent with that degree of learning and skill ordinarily possessed by reputable physicians practicing according to the applicable legal standard of care. . ." As set forth in the Legal Conclusions as a whole, respondent's advocacy did not comply with the standard of care. Discipline is therefore within the Board's discretion, as recognized by the statute's subdivision (g), which expressly provides:

> (g) Nothing in this section shall be construed to prohibit the Medical Board of California from taking disciplinary actions against a physician and surgeon under article 12 (commencing with section 2220).

B. Alternative Medical Care

10. Business and Professions Code section 2234.1 provides:

> (a) A physician and surgeon shall not be subject to discipline pursuant to subdivision (b), (c), or (d) of Section 2234 **solely** on the basis that the treatment or advice he or she rendered to a patient is alternative or complementary medicine . . . if that treatment or advice meets **all** of the following requirements:
>
> (1) It is provided after informed consent and a good-faith prior examination of the patient, and medical indication exists for the treatment or advice, or it is provided for health or well-being.
>
> (2) It is provided after the physician and surgeon has given the patient information concerning conventional treatment and describing the education, experience, and credentials of the physician and surgeon related to the

alternative or complementary medicine that he or she practices.

(3) In the case of alternative or complementary medicine, it does not cause a delay in, or discourage traditional diagnosis of, a condition of the patient.

(4) It does not cause death or serious bodily injury to the patient.

(b) For purposes of this section, "alternative or complementary medicine," means those health care methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the health care method.

(c) Since the National Institute of Medicine has reported that it can take up to 17 years for a new best practice to reach the average physician and surgeon, it is prudent to give attention to new developments not only in general medical care but in the actual treatment of specific diseases, particularly those that are not yet broadly recognized in California.

(Bolding supplied.)

11. As discussed in the Factual Findings and Legal Conclusions as a whole, medical indication did not exist for respondent's withdrawal of SVT's diabetes diagnosis or his substitution of that diagnosis with nesidioblastosis, in the absence of a recognized documentation of hypoglycemia. Further, to the extent respondent's modified Kuroda testing protocol falls within the definition of "alternative or complementary medicine," its use with SVT was outweighed by the risks to her health.

ORDER

Physician and Surgeon's Certificate Number G22683, issued to respondent Roberto Victor Illa, M.D., is revoked pursuant to Legal Conclusions 1 through 6; however, the revocation is stayed and respondent is placed on probation for three (3) years upon the following terms and conditions.

1. **Education Course:** Within 60 calendar days of the effective date of this Decision, and on an annual basis thereafter, respondent shall submit to the Board or its designee for its prior approval educational program(s) or course(s) which shall not be less

than 40 hours per year, for each year of probation. The educational program(s) or course(s) shall be aimed at correcting any areas of deficient practice or knowledge and shall be Category I certified. The educational program(s) or course(s) shall be at respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure. Following the completion of each course, the Board or its designee may administer an examination to test respondent's knowledge of the course. Respondent shall provide proof of attendance for 65 hours of CME of which 40 hours were in satisfaction of this condition.

2. **Medical Record Keeping Course**: Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a course in medical record keeping approved in advance by the Board or its designee. Respondent shall provide the approved course provider with any information and documents that the approved course provider may deem pertinent. Respondent shall participate in and successfully complete the classroom component of the course not later than six (6) months after respondent's initial enrollment. Respondent shall successfully complete any other component of the course within one (1) year of enrollment. The medical record keeping course shall be at respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure.

A medical record keeping course taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the course would have been approved by the Board or its designee had the course been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the course, or not later than 15 calendar days after the effective date of the Decision, whichever is later.

3. **Clinical Competence Assessment Program**: Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a clinical competence assessment program approved in advance by the Board or its designee. Respondent shall successfully complete the program not later than six (6) months after respondent's initial enrollment unless the Board or its designee agrees in writing to an extension of that time.

The program shall consist of a comprehensive assessment of respondent's physical and mental health and the six general domains of clinical competence as defined by the Accreditation Council on Graduate Medical Education and American Board of Medical Specialties pertaining to respondent's current or intended area of practice. The program shall take into account data obtained from the pre-assessment, self-report forms and interview, and the Decision(s), Accusation(s), and any other information that the Board or its designee deems relevant. The program shall require respondent's on-site participation for a minimum of 3 and no more than 5 days as determined by the program for the assessment and clinical

education evaluation. Respondent shall pay all expenses associated with the clinical competence assessment program.

At the end of the evaluation, the program will submit a report to the Board or its designee which unequivocally states whether respondent has demonstrated the ability to practice safely and independently. Based on respondent's performance on the clinical competence assessment, the program will advise the Board or its designee of its recommendation(s) for the scope and length of any additional educational or clinical training, evaluation or treatment for any medical condition or psychological condition, or anything else affecting respondent's practice of medicine. Respondent shall comply with the program's recommendations.

Determination as to whether respondent successfully completed the clinical competence assessment program is solely within the program's jurisdiction.

If respondent fails to enroll, participate in, or successfully complete the clinical competence assessment program within the designated time period, respondent shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. Respondent shall not resume the practice of medicine until enrollment or participation in the outstanding portions of the clinical competence assessment program have been completed. If respondent did not successfully complete the clinical competence assessment program, respondent shall not resume the practice of medicine until a final decision has been rendered on the accusation and/or a petition to revoke probation. The cessation of practice shall not apply to the reduction of the probationary time period.

4. **Solo Practice Prohibition: Pending successful completion of the Clinical Competence Assessment Program set forth in Order Number 3, respondent is prohibited from engaging in the solo practice of medicine.** Prohibited solo practice includes, but is not limited to, a practice where: 1) respondent merely shares office space with another physician but is not affiliated for purposes of providing patient care, or 2) respondent is the sole physician practitioner at that location.

If respondent fails to establish a practice with another physician or secure employment in an appropriate practice setting within 60 calendar days of the effective date of this Decision, respondent shall receive a notification from the Board or its designee to cease the practice of medicine within three (3) calendar days after being so notified. Respondent shall not resume practice until an appropriate practice setting is established.

If, during the course of the probation, respondent's practice setting changes and respondent is no longer practicing in a setting in compliance with this Decision, respondent shall notify the Board or its designee within 5 calendar days of the practice setting change. If respondent fails to establish a practice with another physician or secure employment in an appropriate practice setting within 60 calendar days of the practice setting change, respondent shall receive a notification from the Board or its designee to cease the practice of

medicine within three (3) calendar days after being so notified. Respondent shall not resume practice until an appropriate practice setting is established.

5. **Notification**: Within seven (7) days of the effective date of this Decision, respondent shall provide a true copy of this Decision and Accusation to the Chief of Staff or the Chief Executive Officer at every hospital where privileges or membership are extended to respondent, at any other facility where respondent engages in the practice of medicine, including all physician and locum tenens registries or other similar agencies, and to the Chief Executive Officer at every insurance carrier which extends malpractice insurance coverage to respondent. Respondent shall submit proof of compliance to the Board or its designee within 15 calendar days.

This condition shall apply to any change(s) in hospitals, other facilities or insurance carrier.

6. **Supervision of Physician Assistants and Advanced Practice Nurses**: During probation, respondent is prohibited from supervising physician assistants and advanced practice nurses.

7. **Obey All Laws**: Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California and remain in full compliance with any court ordered criminal probation, payments, and other orders.

8. **Quarterly Declarations**: Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Board, stating whether there has been compliance with all the conditions of probation.

Respondent shall submit quarterly declarations not later than 10 calendar days after the end of the preceding quarter.

9. **General Probation Requirements**:

Compliance with Probation Unit: Respondent shall comply with the Board's probation unit.

Address Changes: Respondent shall, at all times, keep the Board informed of respondent's business and residence addresses, email address (if available), and telephone number. Changes of such addresses shall be immediately communicated in writing to the Board or its designee. Under no circumstances shall a post office box serve as an address of record, except as allowed by Business and Professions Code section 2021(b).

Place of Practice: Respondent shall not engage in the practice of medicine in respondent's or patient's place of residence, unless the patient resides in a skilled nursing facility or other similar licensed facility.

License Renewal: Respondent shall maintain a current and renewed California physician's and surgeon's license.

Travel or Residence Outside California: Respondent shall immediately inform the Board or its designee, in writing, of travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than thirty (30) calendar days.

In the event respondent should leave the State of California to reside or to practice respondent shall notify the Board or its designee in writing 30 calendar days prior to the dates of departure and return.

10. **Interview with the Board or its Designee**: Respondent shall be available in person upon request for interviews either at respondent's place of business or at the probation unit office, with or without prior notice throughout the term of probation.

11. **Non-practice While on Probation**: Respondent shall notify the Board or its designee in writing within 15 calendar days of any periods of non-practice lasting more than 30 calendar days and within 15 calendar days of respondent's return to practice. Non-practice is defined as any period of time respondent is not practicing medicine as defined in Business and Professions Code sections 2051 and 2052 for at least 40 hours in a calendar month in direct patient care, clinical activity or teaching, or other activity as approved by the Board. If respondent resides in California and is considered to be in non-practice, respondent shall comply with all terms and conditions of probation. All time spent in an intensive training program which has been approved by the Board or its designee shall not be considered non-practice and does not relieve respondent from complying with all the terms and conditions of probation. Practicing medicine in another state of the United States or Federal jurisdiction while on probation with the medical licensing authority of that state or jurisdiction shall not be considered non-practice. A Board-ordered suspension of practice shall not be considered as a period of non-practice.

In the event respondent's period of non-practice while on probation exceeds 18 calendar months, respondent shall successfully complete the Federation of State Medical Board's Special Purpose Examination, or, at the Board's discretion, a clinical competence assessment program that meets the criteria of Condition 18 of the current version of the Board's "Manual of Model Disciplinary Orders and Disciplinary Guidelines" prior to resuming the practice of medicine.

Respondent's period of non-practice while on probation shall not exceed two (2) years.

Periods of non-practice will not apply to the reduction of the probationary term.

Periods of non-practice for a respondent residing outside of California, will relieve respondent of the responsibility to comply with the probationary terms and conditions with the exception of this condition and the following terms and conditions of probation: Obey

All Laws; General Probation Requirements; Quarterly Declarations; Abstain from the Use of Alcohol and/or Controlled Substances; and Biological Fluid Testing.

12. **Violation of Probation**: Failure to fully comply with any term or condition of probation is a violation of probation. If respondent violates probation in any respect, the Board, after giving respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an Accusation or Petition to Revoke Probation, or an Interim Suspension Order is filed against respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

13. **License Surrender**: Following the effective date of this Decision, if respondent ceases practicing due to retirement or health reasons or is otherwise unable to satisfy the terms and conditions of probation, respondent may request to surrender his or her license. The Board reserves the right to evaluate respondent's request and to exercise its discretion in determining whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, respondent shall within 15 calendar days deliver respondent's wallet and wall certificate to the Board or its designee and respondent shall no longer practice medicine. Respondent will no longer be subject to the terms and conditions of probation. If respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.

14. **Probation Monitoring Costs**: Respondent shall pay the costs associated with probation monitoring each and every year of probation, as designated by the Board, which may be adjusted on an annual basis. Such costs shall be payable to the Medical Board of California and delivered to the Board or its designee no later than January 31 of each calendar year.

15. **Completion of Probation**: Respondent shall comply with all financial obligations (e.g., restitution, probation costs) not later than 120 calendar days prior to the completion of probation. Upon successful completion of probation, respondent's certificate shall be fully restored.

DATED: January 2, 2018

DocuSigned by:
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MARILYN A. WOOLLARD
Administrative Law Judge
Office of Administrative Hearings

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BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **ROBERTO VICTOR ILLA, M.D.** 1068 East Ave Ste A-1 Chico, CA 95926-1015 Physician's and Surgeon's Certificate No. G22683, Respondent.	Case No. 800-2014-004467 **AMENDED ACCUSATION** OAH No 2016050762

Complainant alleges:

PARTIES

1. Kimberly Kirchmeyer (Complainant) brings this Accusation solely in her official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs (Board).

2. On or about July 14, 1972, the Medical Board issued Physician's and Surgeon's Certificate Number G22683 to Roberto Victor Illa, M.D. (Respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2017, unless renewed.

JURISDICTION

3. This Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

4. Section 2221 of the Code states in relevant part that:

"(a) The board may deny a physician's and surgeon's license to any applicant guilty of unprofessional conduct or of any cause that would subject a licensee to revocation or suspension of his or her license; or, the board in its sole discretion, may issue a probationary physician's and surgeon's certificate to an applicant subject to terms and conditions, including, but not limited to, any of the following conditions of probation:

(1) Practice limited to a supervised, structured environment where the licensee's activities shall be supervised by another physician and surgeon.

(2) Total or partial restrictions on drug prescribing privileges for controlled substances.

(3) Continuing medical or psychiatric treatment.

(4) Ongoing participation in a specified rehabilitation program.

(5) Enrollment and successful completion of a clinical training program.

(6) Abstention from the use of alcohol or drugs.

(7) Restrictions against engaging in certain types of medical practice.

(8) Compliance with all provisions of this chapter.

(9) Payment of the cost of probation monitoring."

"..."

5. Section 2234 of the Code, states:

"The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

"(a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.

"(b) Gross negligence.

"(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

///

"(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

"(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

"(d) Incompetence.

"..."

6. Section 2266 of the Code states: "The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct."

FIRST CAUSE FOR DISCIPLINE
(Gross Negligence)

7. Respondent Roberto Victor Illa, M.D. is subject to disciplinary action under section 2234(b) of the Code in that his care and treatment of patient S.V.T. was an extreme departure from the standard of care. The circumstances are as follows:

8. On or about April 28, 2008, Respondent undertook the care and treatment of patient S.V.T[1]., a 23-year-old female patient, who Respondent diagnosed with diabetes mellitus, with significant hyperglycemia. Respondent treated this patient until **September 30**, 2011. The patient returned to Respondent for treatment on January 15, 2014, when Respondent withdrew his diagnosis of diabetes mellitus. On February 10, 2014, Respondent decided that the patient had nesidioblastosis based on a glucose tolerance test. This glucose tolerance test of February 10, 2014, showed a fasting insulin of 17.0 uU/mL, a glucose of 348 mg/dL, and glucagon of < 134 pg/mL. Patient S.V.T.'s maximum serum glucose was 457 mg/dL one hour after the oral glucose was administered and her lowest glucose was 350 mg/dL four hours after oral glucose. Nesidioblastosis is an extremely rare disorder in adults.

[1] The patient's full name will be disclosed in discovery.

9. In the three year period before April, 2008, patient S.V.T's blood sugars had been controlled with Metformin. However in April, 2008, as she experienced diarrhea while taking the medication, Respondent took her off this medication. The patient's subsequent blood sugars were never well controlled despite the patient taking several other diabetic medications. The patient's glucose went as high as 600 mg/dL in March and April, 2014, which required that the patient be seen in the emergency department where she was given insulin.

10. Respondent's use of two glucose tolerance tests February 4 and 10, 2014, to identify hypoglycemia in a patient with pre-existing diabetes mellitus while the patient was taking multiple anti-hyperglycemic medications is not within the standard of care.

11. Respondent's s diagnosis of nesidioblastosis on February 10, 2014, in the absence of documented hypoglycemia does not meet the standard of care.

12. During the entire period of Respondent's treatment of patient S.V.T. from January, 2014, through April, 2014, Respondent failed to maintain accurate and legible medical records and he frequently reiterated his initial exam notes. Respondent also failed to ever document a foot exam of patient S.V.T in this same timeframe.

13. The only A1C[2] test Respondent ordered was on April 29, 2008, and there was no record of quarterly blood sugars from January, 2011, through March, 2014. An elevated A1C greater than 6.4% was added as an additional criterion to diagnose diabetes in 2009 by the American Diabetes Association. In addition, Respondent never measured urine micro albumen/creatinine levels or lipid levels in this same time period of January, 2011, through March, 2014.

14. Despite Respondent diagnosing patient S.V.T. sixteen times with type 2 diabetes mellitus from April 28, 2008, through September 30, 2011, Respondent eliminated this diagnosis for patient S.V.T. from January 15, 2014, through March 21, 2014, despite extensive documentation clearly supporting the diagnosis of diabetes. The patient had glucose levels in excess of 125 and up to 600 mg/dl, which far exceeded the standard for the diagnosis for diabetes

[2] A blood sugar blood test that can measure blood glucose levels over a three month period.

with fasting glucose levels above 124 mg/dL and random blood glucose over 199 mg/dl.

15. Respondent's failure to maintain accurate and ~~legible~~ complete records, combined with his failure to adequately document a basis for the patient's alleged hypoglycemia, along with his diagnosis of nesidioblastosis, his failure to order A1C tests quarterly for the patient and his withdrawal of the diagnosis of diabetes mellitus for the patient from January, 2011, through March, 2014, collectively constitutes an extreme departure from the standard of care in violation of section 2234(b) of the Code.

SECOND CAUSE FOR DISCIPLINE
(Repeated Negligent Acts)

16. Respondent Roberto Victor Illa, M.D. is subject to disciplinary action under section 2234(c) in that he engaged in repeated negligent acts in his care and treatment of patient S.V.T. The circumstances are as follows:

17. Complainant re-alleges paragraphs 8-14 above and incorporates them by reference herein as though fully set forth.

18. Respondent's failure to maintain accurate and ~~legible~~ complete records, combined with his failure to adequately document a basis for the patient's alleged hypoglycemia, along with his diagnosis of nesidioblastosis, his failure to order A1C tests quarterly for the patient and his withdrawal of the diagnosis of diabetes mellitus for the patient from January, 2011, through March, 2014, collectively and in any combination of two of five alleged failures constitutes repeated negligent acts in violation of section 2234(c) of the Code.

THIRD CAUSE FOR DISCIPLINE
(Failure to maintain accurate records)

19. Respondent Roberto Victor Illa, M.D. is subject to disciplinary action under section 2266 in that he failed to keep accurate records. The circumstances are as follows:

20. Complainant re-alleges paragraphs 8 and 15 above and incorporates them by reference herein as though fully set forth.

21. From the period of January, ~~2011~~ 2014, through March, 2014, Respondent failed to keep accurate and complete records of his care and treatment of patient S.V.T.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Medical Board of California issue a decision:

1. Revoking or suspending Physician's and Surgeon's Certificate Number G22683, issued to Roberto Victor Illa, M.D.;

2. Revoking, suspending or denying approval of Roberto Victor Illa, M.D.'s authority to supervise physician assistants, pursuant to section 3527 of the Code;

3. Ordering Roberto Victor Illa, M.D., if placed on probation, to pay the Board the costs of probation monitoring; and

4. Taking such other and further action as deemed necessary and proper.

DATED: _____

KIMBERLY KIRCHMEYER
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

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